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LANDSCAPE AND MITIGATION FACTORS IN AQUATIC ECOLOGICAL RISK ASSESSMENT.

Volume 1. Extended Summary and Recommendations

The Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment

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FOREWORD

Introduction

This foreword is written on behalf of the FOCUS Steering Committee in support of the work of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. The work reported here is for use in support of the European Union review of active substances of plant protection products under Council Directive 91/414/EEC of July 15 1991.

FOCUS (FOrum for the Coordination of pesticide fate models and their USe) is an organisation that was established under the auspices of DG SANCO to develop approaches to environmental exposure assessment issues under Directive 91/414/EEC. The aim of FOCUS is to develop guidance for notifiers and Member States concerning appropriate methods for calculating exposure concentrations for EU dossiers on plant protection products (Annex I). Whilst not specifically targeted at Member State review procedures (Annex III), the approaches developed within FOCUS may also have applications at Member State level.

Over recent years, significant advances have been made in the development of exposure assessments for surface waters through the activities of FOCUS working groups on this topic, most recently with the release of the FOCUS surface water scenarios (FOCUS, 2002). Whilst these approaches have led to the development of harmonised approaches for conducting lower-tier exposure assessments (Step 1, 2 & 3), to date little guidance has been available on the topics of higher-tier exposure assessments and the implementation of mitigation measures suitable for managing the risks identified in the reasonable worst-case assessments developed at FOCUS surface water Step 3. The need to develop such approaches to promote the sustainable use of plant protection products was identified as a high priority need by the FOCUS Steering Committee. Consequently, a working group was established in June 2002 to review potential approaches to higher-tier (Step 4) surface water exposure assessments and mitigation measures. ***The remit of the group was to review the current state-of-the-art, where possible recommending approaches that could be implemented forthwith, and to also produce recommendations for where further work is needed. The working group considered approaches suitable for supporting the assessment necessary for authorisation on a Community level, but also those that could be applied in risk assessments to support national registration.*** The formation and main work of the group preceded the formal splitting of responsibility for risk assessment and risk management between the European Food Safety Authority (EFSA) and the European Commission, respectively. The reader may thus find these two disciplines discussed in sequence within a particular topic, rather than formally segregated within the structure of the report. Whilst the group was principally concerned with addressing the aquatic compartment, certain of the approaches discussed are also relevant to the terrestrial compartment. Due to the resources and information available, however, the majority of the effort was focused on aquatic issues.

Over the last two years, the FOCUS working group on Landscape and Mitigation Factors in Ecological Risk Assessment has developed extensive reviews in four sub-topic areas, namely:

- Development of harmonised approaches to mitigation measures;
- Incorporating modelling refinements and mitigation into aquatic exposure assessment at Step 4;
- Methods and data for describing agricultural landscapes;
- Ecological considerations in landscape assessments.

The following report provides a concise overview of the discussions and recommendations of the group (Volume 1 – summary report) and also the detailed technical reviews produced by each of the subgroups (Volume 2 – detailed technical report). The documents provide a general framework for refining aquatic risk assessments that is intended to be used as guidance and not as a prescriptive set of requirements. The most appropriate way to refine the assessment will depend on the usage pattern and properties of the chemical, so adoption of approaches discussed in the reports will be on a case-by-case rather than a routine basis.

The working group held six meetings between November 2002 and March 2004. A draft report was submitted to two rounds of comment by Member States terminating in October 2004. This draft was revised at a further meeting of the working group and version 1.0 of the report was finalised by the FOCUS Steering Group in May 2005. In response to a request from EFSA, the Scientific Panel on Plant Protection products and their Residues issued an opinion on version 1.0 of the report in December 2006. Version 2.0 has been revised to take account of the Panel's opinion. The reader is referred to the full text of the opinion (EFSA, 2006) and it is recommended that the opinion is considered alongside version 2.0 of FOCUS working group's report.

Summary of Working Group Outputs

Landscape-level risk assessment can be conducted in two ways. Firstly, the influence of the surrounding landscape on the edge-of-field exposure of surface water can be examined by considering the structure of the area of landscape (e.g. land use, soil types, proximity of crop and water) surrounding the water body of concern. Secondly, an assessment can be made for an entire landscape incorporating the spatial relationship between water bodies over a large area such as a catchment. The Working Group recommends that at present, Step 4 assessments are focused on the former of the two approaches (landscape influence on edge-of-field assessments) because:

- Tools for spatially-distributed assessment of exposure and effects at the catchment level are not fully developed.
- The precedent of the current review process under Directive 91/414/EC has generally focused assessments on single active ingredients whereas catchment assessments require the consideration of multiple compounds and stressors.
- Point source inputs of active ingredients are a confounding factor at the catchment level.

Substantial developments have taken place over recent years that mean that approaches for assessing the influence of the landscape on the edge-of-field surface water body can be implemented forthwith. Similarly, mitigation measures are available that can be used in combination with higher-tier modelling to determine acceptable levels of exposure. The Steering Committee supports the recommendation of the Work Group that such higher-tier approaches are included forthwith in the review of plant protection products under Directive 91/414/EEC. The Work Group has produced detailed guidance on how such approaches could be used and this is summarised below.

A review of ***mitigation measures*** currently implemented by Member States and a collation of the approaches available in the scientific literature indicated that there are a number of suitable approaches currently available for mitigating the exposure of surface water from plant protection products. The working group assessed the technical applicability of the mitigation measures. Economic aspects were outside the scope of the group. Enforceability was considered in a general way (for example, most measures are implemented in one or more Member States, suggesting that enforcement should be feasible). However, true enforceability is a national issue that will vary according to legislative framework, possibilities for policing, profile of the farming community etc., and was thus considered beyond the scope of the working group. The report details generic options for mitigation that might be applied at Community level and within national authorisation procedures. However, decisions on whether or not a particular measure is compatible with local conditions and enforcement possibilities must be taken by the appropriate authority in a particular Member State. There are a number of approaches to spray drift mitigation (buffer zones, application technology and windbreaks) that could be included immediately to mitigate exposure where needed. It is proposed that a maximum cap of 95% reduction in exposure via spray drift is applied at Annex I, although several methodologies allow mitigation up to a maximum of 99%. For runoff exposure, although less developed than spray-drift mitigation, techniques are available for immediate use for mitigating exposure where needed by up to a maximum reduction of 90% (through the use of filter strips and application restrictions). Mitigation of drainage inputs is least developed, although application restrictions (based on soil type and season) could be used to essentially eliminate drainage inputs on vulnerable soils. It will be difficult to guarantee such elimination in practice, so a maximum cap is proposed for use at Annex I of 90% reduction in exposure via drainage. Additional work is recommended to further harmonise approaches for assessing spray-drift mitigation, and to further develop mitigation options for runoff and drainage.

Considerations of the potential for ***incorporating modelling refinements and mitigation into exposure assessment at Step 4*** identified three main refinement options. First, relatively simple changes can be made to the existing FOCUS Step 3 scenarios by refining input parameters for the chemical or scenario to make them more precisely reflect the potential exposure being assessed. Secondly, mitigation measures can be incorporated into Step 3 scenarios (resulting in a Step 4 calculation). Thirdly, new scenarios could be developed for use at Step 4 to more precisely reflect the range of environmental and agronomic conditions for use of a plant protection product at a local or regional scale. The location of such new scenarios should follow the procedures adopted by the FOCUS surface water scenarios group. All of these approaches to Step 4 calculations are now available and should be implemented forthwith in the European Union approval process. The development of further modelling tools was outside the remit of the current working group, but detailed recommendations are put forward in the report on how to refine the modelling using tools that are already available. A modelling tool called SWAN has been developed independently to support Step 4 calculations. Where modelling is refined to reflect local conditions, it is imperative to establish the degree to which conditions are representative and/or protective of the wider usage area. Again, methodologies are proposed to support such assessments. The work on Step 4 exposure assessment builds on the outputs of the FOCUS surface water scenarios group and thus considers mainly exposure via spray drift, surface runoff and drainflow. Where other routes of entry are significant, these must also be considered in refining the exposure estimate at Step 4 (e.g. wet or dry deposition from air, exposure from direct entry of granular formulations during application).

A wide range of ***methods and data for describing agricultural landscapes*** are now available and these can be used to develop refined exposure assessments at Step 4, principally through the use of geographical information systems (GIS). The tools allow a quantitative description of the agro-ecosystem landscape, enabling relationships between cropped land and areas containing non-target organisms to be explored. A number of technical recommendations have been developed to deal with questions of scale of analysis, site selection, data availability, and setting landscape assessments in a broader regional or even EU context. These tools and data can be used to develop the modelling approaches described above.

Risk assessment at Step 4 should not only consider exposure assessment, but all options for refinement, including ***ecological considerations***. One important development in this area would be the definition of the ecological characteristics (biotic and abiotic) of the FOCUS surface water scenarios. Information of this sort could be used in the future to refine both the exposure and effects assessment. One of the challenges confronting risk assessors in light of the FOCUS surface water scenario developments is the time-varying exposure profile of concentration produced at Step 3, which can be at odds with the maintained exposure conditions in standard toxicity tests. A review of potential approaches for addressing this has been conducted. Furthermore, moving to the landscape level provides opportunities for considering recovery potential, both internally (from within the water body of concern) and externally (from neighbouring waters). Potential approaches for developing these techniques have been reviewed.

Please note that some of the recommendations of the working group reflect the current technical state of the art rather than what may be possible to implement in regulatory practice. Some of the issues may need to be further discussed and decided upon by policy makers at the European Union level and at Member State level.

Requirements for further work

Recommendations for implementation and further work for each of the subgroup discussions are included in the summary (Volume 1) and detailed technical (Volume 2) reports. In its consideration of the state of development and potential future use of the landscape and mitigation approaches at Step 4, the Working Group made the following conclusions on the priorities for future work:

1. A new working group should be considered to further improve landscape analysis, modelling and mitigation approaches. There is a need to harmonise methods for producing spray drift data and to develop harmonised spray drift models, and an

urgent need for more work on drainage and runoff, and issues such as simulating irrigation patterns in specialist crops. There is also a need to formalise the generation of landscape factors for consistency, as well as the appropriate scale to use for these analyses. This group could also contribute to the upgrading of the existing FOCUS surface water tools to facilitate Step 4 calculations.

2. A new working group should be considered to develop the ecological characteristics of the FOCUS surface water scenarios for use in higher-tier exposure modelling and effects assessments. It is anticipated that such a group would need to be similar to the FOCUS surface water scenarios group in terms of size and scope.

3. Whilst the work presented here has focused on aquatic systems, many of the methods and approaches may be transferable to the terrestrial compartment. Nevertheless, complementary approaches should be developed for terrestrial systems in the future. Lower-tier terrestrial exposure assessment has not been addressed via FOCUS and it would be essential to build on existing guidance and methods developed under other initiatives.

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1 INTRODUCTION

1.1 Establishment of the FOCUS Work Group on Landscape and Mitigation Factors in Aquatic Ecological Risk Assessment

Ecological risk assessment in the EU is evolving rapidly into a well-structured, tiered approach to assess potential risks, with substantial developments having taken place in both the exposure and effects sides of the risk equation over the last five years. Much of the recent development of tiered exposure assessment has come about through the efforts of the FOCUS groups. The framework for assessing the effects aspects of aquatic ecological risk assessment has also become increasingly harmonised, and higher-tier effects approaches are now well-established (e.g. via HARAP and CLASSIC and the EU Aquatic Guidance Document).

To date, the work within FOCUS has concentrated on the lower and 'medium' tiers. Some general guidance concerning higher-tier aquatic exposure assessment is included in the FOCUS surface waters report (FOCUS, 2002). However, the recommendation of this group was that further work was necessary to develop so-called Step 4 approaches which take into account local and regional factors, and potential mitigation measures. There is a need to further refine the tiered approach to exposure assessment by developing harmonised approaches to include landscape-level and mitigation factors.

A number of activities have begun at Member State level to evaluate the potential uses of landscape and mitigation factors in pesticide risk assessment (e.g. LERAP in the UK, the former UBA/BBA 'ABCD' scheme in Germany), but broader guidance has not yet been developed. Indeed in many EU Member States, it is not clear how mitigation measures will be applied. The development of harmonised guidance (at least as far as the scientific principles are concerned) in this area would be of benefit.

At the highest tier, risk assessment and mitigation should go hand-in-hand because measures that are used to refine potential exposure assessments can also be used to define appropriate mitigation strategies (e.g. non-sprayed areas or headlands; riparian trees or vegetation; variations in agronomic practices). For this reason, a FOCUS group to evaluate potential applications of landscape and mitigation factors in aquatic ecological risk assessment was established in June 2002. The discussions and reviews of this group are captured in this report.

1.2 Concepts and remit of the group

The overall remit of the group was to:

1. Conduct a scoping exercise to investigate options and feasibilities for including landscape and mitigation factors in higher-tier exposure assessments, similar in concept to the first FOCUS groups working on groundwater and surface water.

2. Produce a review of the state of the art in landscape and mitigation factors in exposure assessment, and to make recommendations for future FOCUS groups to develop this area further.

Specifically, the group was asked to:

1. Identify and review the available data and approaches to risk mitigation (for spray drift, runoff and drainage).

2. Where possible, develop harmonised approaches for quantifying the impact of these measures on pesticide exposure in aquatic and terrestrial non-target environments in such a way that the values can be used in higher-tier risk assessment.

3. Develop a listing of data that would help to reduce uncertainties in higher-tier exposure assessment (particularly at the 'landscape level').

4. Identify the key holders of such data, and where possible, coordinate an approach for making such data available to Member States and industry for risk assessment purposes (addressing the necessary commercialisation aspects of proprietary data).

5. Identify where there are key short-comings in scientific understanding and/or databases and make recommendations for further research and/or data collection.

1.3 Overview of report structure

The Work Group reviewed a large amount of technical information within four main topic areas for which subgroups were established. The subgroups were categorised as follows:

- Risk mitigation
- Exposure modelling
- Landscape analysis
- Ecology

Each of these subgroups has produced a detailed technical review for its subject area. The scope of the review exercise that was conducted is summarised in Table 1 and detailed reports on each topic are contained in Volume 2 of this report. Section 4 of this report gives some key recommendations on general principles for higher-tier exposure assessment. This is followed by four sections covering the outputs of the subgroups and a collation of recommendations for future activities. The appendices to this volume provide illustrations of possible approaches to step 4 refinements. Appendix 1 gives one possible approach to developing a new exposure scenarios. Illustrations of Step 4 calculations address a use of site-specific catchment modelling (Appendix 2), a possible approach to refine estimates of exposure via drainflow (Appendix 3) and a landscape analysis to refine estimates of exposure via spray drift (Appendix 4). Note that the appendices are illustrative only; they do not reproduce regulatory submissions in terms of the level of detail required and only represent a few out of many options for refinement at Step 4. The PPR panel has provided detailed opinions on these examples (PPR, 2006).

Table 1. Topics covered by the review of technical information (Volume 2)

Risk mitigation
Current practice in risk mitigation within the framework of 91/414/EEC
Options to mitigate exposure via spray drift
Options to mitigate exposure via surface runoff
Options to mitigate exposure via drainflow
Mitigation measures applying to all routes of exposure
Exposure modelling
Refinements to FOCUS Step 3 surface water modelling (Step 4 calculations): edge of field modifications; incorporating mitigation measures; more complex modelling
Modelling at the catchment scale
Probabilistic risk assessment
Use of monitoring data in exposure assessment
Landscape analysis
Unit of analysis
Site selection process
Landscape factors for higher tier exposure assessment
Exposure estimates for higher tier assessment
Relating landscape factors to a larger area
Supporting information for higher tier exposure assessment
Use of remotely-sensed data in landscape characterisation
Data layers and contacts for spatial analyses
Ecology
Overview of current legislative background and protection aims
Factors that influence community composition
Abiotic and biotic factors that influence effects
Ecological factors that influence exposure
Landscape factors that influence effects and recovery

2 GENERAL PRINCIPLES

2.1 Problem Formulation at Step 4

As with all levels of risk assessment, the first critical component of a Step 4 risk assessment is that of problem formulation. This includes the development of assessment endpoints, conceptual models, and an analysis plan:

- Assessment endpoints are measurable ecological characteristics that represent the management goal(s). Assessment endpoints include both the ecological entity to be protected and an attribute of that entity that is potentially at risk, important to protect, measurable and has easily discernible meaning.

- Potential interactions between assessment endpoints and stressors are explored by developing conceptual models that link anthropogenic activities with stressors and evaluate inter-relationships among exposure pathways, ecological effects, and ecological receptors.

- The analysis plan justifies what will be done as well as what will not be done in the assessment, describes the data and measures to be used in the risk assessment, and indicates how risks will be characterised.

Step 4 assessments may apply a wide variety of different methods and data and there is a significant risk that the work may not address the intended objectives unless a full problem formulation is undertaken.

2.2 Definition of a Landscape

The working group arrived at a very general definition of the term "landscape" which places the discussion of landscape factors into context. A landscape is an assembly of inter-related features created over time by the action of climate and biology (including human influences) on the underlying topography and geology. These latter two factors affect the rate of weathering and determine the distribution of soils in the landscape. Typically soils in upland areas are being depleted by erosion and leaching, while soils in the lowland areas are characterised by accumulation of sediment and nutrients. The prevalence of different types of water bodies in the landscape is also a function of these same factors because topography and geology determine both the type of hydrological network, and the shape and flow velocity of streams and other water bodies.

A landscape consists of both the upstream and downstream elements because they are interdependent. However, the elements within a landscape can be very different (e.g. a mountain stream and a flood plain).

At the level of a landscape, groundwater and surface water are closely interrelated. Typically, water infiltrating to groundwater in the upper part of a catchment reappears as baseflow in lower parts. Water in ponds and streams may infiltrate to groundwater through the bottom of these in parts of the landscape, while streams in other parts receive baseflow; or the water dynamics of a pond may be determined by groundwater variations in the surrounding area as seen in many wetlands. A very strict distinction between surface water and groundwater at this level is therefore somewhat artificial.

Land use is often intrinsically linked to the original natural conditions of the landscape e.g. arable agricultural areas are often found in particular landscape elements (characterised by, for example, limited slopes and a range of preferred soil types). Anthropogenic factors may further modify the natural conditions in landscape elements. Initially land use is influenced, for example, by drainage, cutting of vegetation in ditches and streams, building of structures, straightening and lining of streams.

Landscape characterisation often refers to the quantification of the physical factors discussed above, using available environmental, spatial, and statistical data using an information system (such as fate and exposure models, geographic information systems, etc.). This quantification encompasses individual characteristics and units within the landscape (such as land cover, fields, water bodies, soil types, etc.). It may also include the relationship between these units within the landscape (e.g. connectivity of water bodies within a catchment, relationship between groundwater and surface water within a catchment). The ability to characterise the physical factors and processes within a landscape is limited by input data, as well as the ability to appropriately model and quantify the landscape. The terms 'landscape-level information' and 'landscape-level processing' are subsequently used in this report in relation to the quantification of the physical characteristics of the landscape within exposure and fate models, and GIS.

Landscapes often combine multiple habitats for both aquatic and terrestrial species. As far as aquatic species are concerned, habitats are in general limited by the bounds of the water body, but several habitat types may exist within the same water body. Connectivity between habitats may be physical (through hydrological connections between water bodies) but also biological (through movement of organisms), adding a spatial dimension to the ecological characterisation of the landscape. Groups of organisms dispersed in the landscape in this way are referred to as metapopulations. The scale at which these metapopulations operate is dependent on the size of the organism and its dispersal ability.

2.3 Scale of the risk assessment

One complicating factor in moving to the landscape level is that of determining the appropriate scale for the assessment. This is strongly influenced by societal factors such as risk perception/acceptance and protection aims. The scale of ecological risk assessment for the aquatic compartment based on FOCUS Step 3 procedures is defined by the exposure assessment. This clearly operates at the scale of a single field (referred to as field scale). Although inputs to the FOCUS surface water stream are considered from an area that is composed of more than one field, the calculations are based on extrapolation of losses from a single field together with a simple assumption about the percentage of the total area treated. Likewise, the effects characterisation based on the Guidance Document on Aquatic Ecotoxicology (DG SANCO, 2002) is grounded at field scale, considering representative sensitive species and static test systems that have potential for internal recovery and limited potential for external recolonisation.

One of the tasks of the work group was to consider how landscape factors could influence the risk to non-target organisms potentially exposed to pesticides and to make recommendations as to whether these factors could be incorporated at higher tiers to improve the realism of the risk assessment. It is clear that a range of landscape factors greatly influence ecological risk. A central question addressed by the work group thus becomes: What is the most appropriate scale for ecological risk assessment?

For simplicity, two approaches can be defined to describe the influence of landscape on risk. The first comprises dividing the landscape into discrete parcels to investigate how parameters influencing risk at the field scale are distributed within the wider environment. This approach considers variability within the landscape (by considering multiple edge-of-field situations), but does not consider the interaction between parts of the landscape with different properties (soil type, topography, land use, pesticide inputs etc). The second approach considers the landscape as a true continuum that is both varying in properties and interacting through a whole range of processes. The first approach leaves the risk assessment at the field scale (albeit with an improved description of how the environment varies at that scale), whereas the second is a clear up-scaling from current procedures. Table 2 illustrates the difference in approach with examples of assessment techniques that belong to each.

Table 2. Approaches considered to include the influence of landscape factors at either the field scale (by considering multiple edge-of-field assessments) or the true landscape scale (by considering larger areas as inter-connected units)

Approach at the field scale (discussed in detail in the report)	Approach at the true landscape scale (reviewed but requiring further work)
Refined field-scale modelling	Catchment modelling
Primarily consideration of internal recovery potential of the population with only limited external recolonisation	Consideration of internal and external recovery potential via meta-population dynamics
Exposure calculated for water bodies as discrete units proximate to the treated crop ('edge-of-field')	Exposure calculated for all water bodies as inter-connected units ('catchment')
Runoff from single fields	Surface water routing (via various processes) through the catchment
Upstream loading calculated with a single value for modelling	Upstream loading calculated dynamically for each water body
Assessment of individual compounds	Consideration of multiple compounds and stressors

The Work Group considered both the scientific and regulatory basis for undertaking risk assessment at the landscape scale and came to the following conclusions:

[1] There are scientific tools which would be required for both exposure and effects assessment. These include models to predict exposure at the catchment level and approaches to predict external recovery of impacted populations via recolonisation. Several questions need to be answered on how to interpret catchment-scale exposure with respect to ecological relevance (e.g. how to consider very large concentrations in ephemeral water bodies exposed during the drying phase when the water is very shallow). It was agreed that tools to support predictions at the landscape scale for both fate and effects are developing rapidly. However, the state-of-the-art and predictive capability of existing tools is insufficient to support incorporation into risk assessment for Annex I listing at the present time.

[2] The group considered that potential effects from multiple stressors (both pesticidal and other) would need to be considered at the catchment scale. This is because (i) combined influences from several stressors are more likely at the catchment scale

than at the edge-of-field where a single stressor may exert a dominant effect; and (ii) potential for recolonisation from areas not impacted by a particular stressor may be compromised if other stressors are acting at the scale of assessment. There is a general understanding of the influence of mixtures of stressors with a single mode-of-action and mathematical approaches to describe the combined effect are available (see Volume II Section 3.3.2). However, the framework for pesticide authorisation generally assesses single plant protection products.

[3] Evidence from monitoring studies demonstrates that contamination of surface waters by pesticides arising from point sources (e.g. via sewage treatment works, spills, farmyard washoff) can often be a significant proportion of the total loading at the catchment scale. Point source contamination most frequently arises from accidental spillage during handling/disposal activities that is precluded under Good Agricultural Practice. Enforcement of the principles of Good Agricultural Practice falls within the remit of 91/414/EEC and good progress in reducing point source inputs has been demonstrated for campaigns targeting farmer education (e.g. Kreuger et al., 1999). As accidental releases as point sources are controlled at this general level, the current regulatory exposure models do not include the effects of point source loading. Again, there is an implicit restriction in the scale of risk assessment for pesticide authorisation.

The three points outlined above are limitations on the potential to broaden the scale of regulatory risk assessment from field scale to catchment scale. The Work Group recognises that catchment-scale assessments may be appropriate at Member State or regional level where data have been generated specifically to validate the approach (e.g. scenario-based exposure modelling with PESTSURF in Denmark; Styczen et al., 2004). In addition, suggestions are made for work required to further develop approaches applicable at the catchment scale.

[Recommendation 1] For the present time, the Work Group recommends that ecological risk assessment for the aquatic compartment to support Annex I listing should remain at the field scale. The influence of landscape on the risk assessment should be evaluated by dividing the landscape into parcels in order to investigate how parameters influencing risk at the field scale are distributed within the wider environment. The remainder of the report makes specific recommendations for how this may be done.

3 RECOMMENDATIONS FOR MITIGATION OF RISK TO THE AQUATIC COMPARTMENT UNDER 91/414/EEC

3.1 Risk mitigation measures currently used in EU Member States to protect aquatic life within the authorisation procedure of plant protection products

A review was undertaken to assess differences in aquatic risk mitigation measures currently applied by different Member States. Representatives of the different Member States were surveyed and literature sources were collated. The results of the review are summarised in Table 3, and a more detailed description of measures in different Member States is provided in Volume 2 Section 1.2. A broad view of risk mitigation measures is taken and these are defined as all measures and conditions that mitigate risk compared with the standard use situation considered during risk assessment in accordance with the Uniform Principles. This means that not only active mitigation such as implementation of a no-spray (or no-crop) buffer zone, but also the absence of a vulnerable situation (e.g. large and or flowing water bodies with large dilution potential) is considered at this stage.

The current position on the stipulation of mitigation measures during authorisation is variable, although mitigation options for all potential exposure routes are already considered by several Member States. Whereas risk mitigation during authorisation is routine in some Member States, measures are only applied post-authorisation at the regional or local scale in others. Mitigation of risk arising from spray drift is much further developed than that for exposure via surface runoff or drainflow. No-spray buffer zones are the most widely used mitigation measure although maximum widths and local conditions considered in their adoption vary considerably. Drift-reducing techniques are also considered in several Member States.

Table 3. Examples of risk mitigation measures currently used in European Member States (includes examples of post-authorisation and voluntary measures)

Member State	Spray drift			Surface runoff	Drainflow
	No-spray buffer zone	Drift-reducing techniques	Other		
Austria	Up to 50 m	Yes	Bankside vegetation; application type	-	-
Denmark	By crop (up to 20-50 m)	-	-	-	Application window
Finland	10-25 m	-	-	-	-
France	Mitigation devised and implemented based on local conditions	-	-	Mitigation devised and implemented based on local conditions	Mitigation devised and implemented based on local conditions
Germany	Up to 20 m	Yes	-	Grassed buffer zones; minimum tillage; detention ponds	Application window; soil type
Greece	Up to 20 m	-	-	-	-
Ireland	By crop (up to 5-50 m)	-	Dry ditch	-	-
Italy	Up to 50 m	Yes	-	-	-
Netherlands	0.25 - 14 m	Yes	Windbreak	-	-
Portugal	By crop (up to 5 - 40 m)	Yes	-	Grassed buffer zones; minimum tillage	-
Spain	Up to 5 - 50 m	Yes	-	Application window; grassed buffer zones	-
Sweden	By water body (1 - 10 m)	Yes	Wind speed and direction; field size; temperature	-	-
UK	By crop (up to 5 - 50 m)	Yes	Water body type and size; windbreak	-	Application window

3.2 General principles for implementing risk mitigation measures under 91/414

The Work Group reviewed current practice in risk mitigation for pesticides across Europe and examined the literature investigating the efficacy of individual mitigation measures. ***[Recommendation 2] There is already sufficient evidence to implement certain measures into ecological risk assessment and it is recommended that this is done immediately. Authorisations of products that present unacceptable ecological risk under standard use conditions can be made subject to the application of suitable restrictions ensuring mitigation of the risk. Whilst a continuous scale to quantify the reduction in exposure associated with a given mitigation measure is feasible in risk assessment, this would not be pragmatic when implementing the measures. It is recommended that implementation of mitigation measures would be facilitated by grouping the extent to which a measure reduces exposure into categories (e.g. 50, 75, 90 and 95%). The Work Group has adopted a reasonable worst-case approach in assigning measures to different categories (e.g. exposure reductions based on larger datasets are assigned as a nominal 10th percentile of the actual range of efficacy).***

The current approach for setting risk mitigation measures in the EU (principally done using spray drift buffers) is to quantitatively include the precise influence of the mitigation measures in the risk assessment process (e.g. by calculating to what extent spray drift exposure is reduced with distance from the crop using the relationship between drift deposition and distance). However, the situation is becoming more complex because there are already a range of techniques that can be applied under the variety of use conditions in the EU. Consequently, in order to simplify and clarify, it is proposed to categorise mitigation measures into a number of groupings according to the extent by which they reduce exposure and hence risk. Therefore it is proposed to implement risk mitigation categories of 50, 75, 90 and 95% that can be used in the EU risk assessment at Annex I. For a particular use, where mitigation is required, it would then be possible to state the extent of mitigation that is needed for the particular entry route of concern to achieve acceptable levels of exposure (the amount required might vary according to usage or environmental conditions in a particular Member State). At Annex III, it would then be the responsibility of the Member States to decide which mitigation measures were appropriate and practical to achieve the needed reduction in exposure for their particular circumstances.

The topic of risk mitigation measures needs to span both regulatory procedures at European level leading to the listing of plant protection products on Annex 1 and authorisation procedures at Member State level where individual measures must be implemented. It is unlikely that the implementation of mitigation measures can be harmonised at Member State level in the short-term because: (i) there is large variability in the status of measures currently implemented to mitigate risk (Volume 2, Section 1.2); (ii) there are different legal frameworks and enforcement possibilities in the different Member States; (iii) individual measures may be particularly suited to specific use conditions; and (iv) there are differences in agricultural practice and regulatory assessment procedures at Member State level (e.g. the use of locally collected data to calculate exposure via spray drift). ***[Recommendation 3] For these reasons, it is recommended that a sequential procedure is adopted for incorporating mitigation measures into ecological risk assessment (Figure 1), noting that the level of protection remains a matter for the risk manager.*** Where it is considered that a risk mitigation measure is required to protect non-target organisms, the structure of the recommended system is as follows:

[1] There should be a harmonised listing of the level of mitigation afforded by different mitigation measures. An initial list is presented below. The purpose of the list is to support the authorisations of plant protection products at the European level. For the reasons outlined above, it is not intended that the listing should be considered as mandatory, as different Member States will have varying use conditions and differing potential to implement a specific measure. The listing should be reviewed and updated periodically by an appropriate FOCUS Work Group.

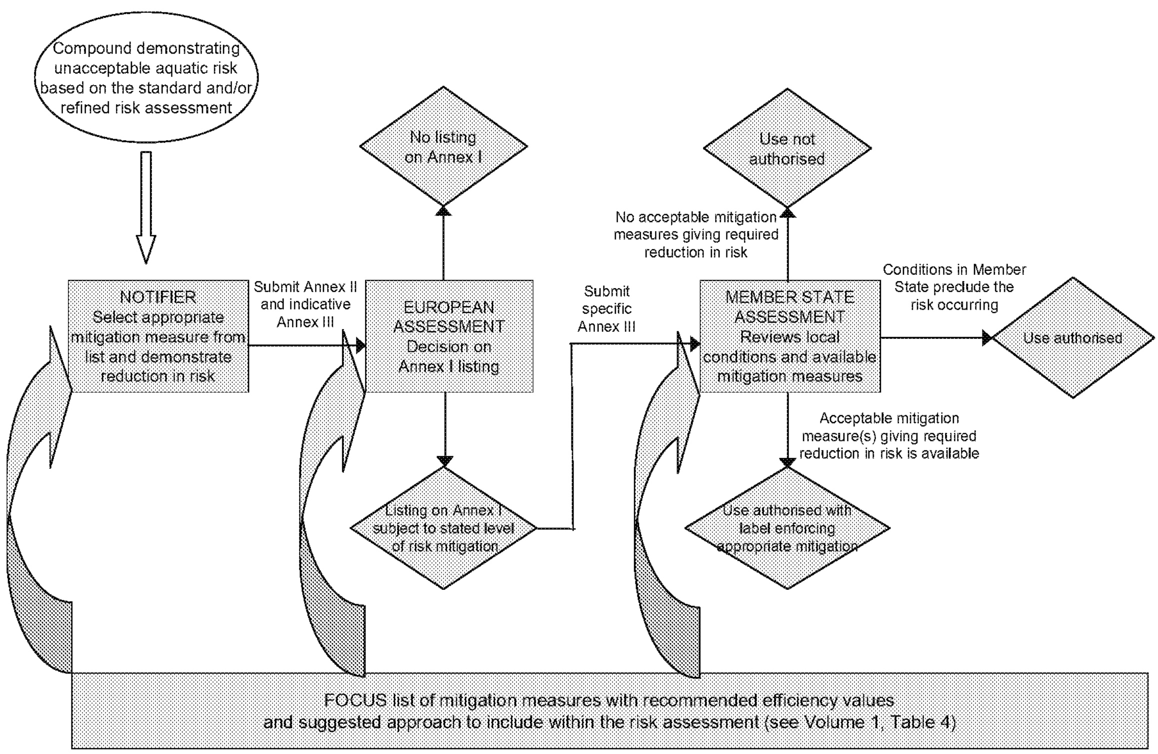
[2] The notifier will need to demonstrate the efficacy of one or more measures through a suitable refinement of the risk assessment (see Section 6.2).

[3] Within the EU registration process, the actual measure to be applied to mitigate risk should not be specified. Rather, the listing on Annex I should state that the decision to authorise the active substance was made on the basis of a mitigated risk and the level of mitigation that must be achieved for a particular input route in the different scenarios to assure safe use. It is possible to establish the level of mitigation that can be achieved for different measures with proved efficiency; such a listing implies that the maximum level of mitigation specified during Annex I listing is capped and that it will not be possible to authorise products where an unrealistic mitigation of risk would be required (see Section 5.3).

[4] Individual Member States must decide on national authorisations for products subject to appropriate risk mitigation and within the context of protection targets established by the risk manager. In so doing, they should consult the harmonised listing of mitigation measures for those approaches that are both appropriate and practicable to

implement. Some mitigation measures will vary between Member States (e.g. the mitigation afforded by drift-reducing techniques may vary with standard machinery set-up and/or environmental conditions). Here, it would be appropriate to supplement the standard listing with alternative classifications at Member State level.

Figure 1. Schematic showing the recommended approach to incorporate risk mitigation within the approvals process under 91/414/EEC (note that the level of protection remains a matter for the risk manager)



3.3 Mitigation measures suitable for incorporation into ecological risk assessment

It was agreed that several criteria must be met before a specific mitigation measure can be recommended for inclusion in the risk assessment and for subsequent implementation into risk management:

[1] The measure must be practicable with a reasonable ***possibility*** of enforcement. It was beyond the scope of the working group to review the enforceability of a measure in individual Member States, but clearly successful mitigation depends on the measure being operational, controllable and backed by suitable enforcement.

[2] There must be a weight of evidence to demonstrate the efficacy of the measure under European (or directly correlated) conditions. The evidence must be quantitative so that the effect of the mitigation can be described numerically.

[3] The risk assessment based on FOCUS Step 3 is complex and considers multiple routes of exposure (spray drift and either drainflow or runoff). Methods must be available to include mitigation against a single route of entry into exposure assessments so that the total reduction in risk can be calculated.

The Work Group examined measures aimed at mitigating exposure via spray drift, surface runoff and drainflow. There are examples of measures for each exposure route where there is sufficient evidence of efficacy to recommend immediate inclusion within the risk assessment. These are summarised in Table 4 and discussed in Sections 5.4 to 5.6 below. ***[Recommendation 4] Whereas mitigation possibilities for spray drift are generally well-developed, further work is recommended as a priority to develop mitigation possibilities for exposure via surface runoff and drainflow.***

Mitigating influences operating at the landscape level were also considered, though in less detail. For example, the external recovery potential associated with inter-connected water bodies or terrestrial habitats in differentially contaminated landscapes will mitigate risk from specific contaminants. ***[Recommendation 5] It was agreed that the impact of such influences may be significant and that further work is required to develop and evaluate such approaches. However, as the scale of the risk assessment currently remains at field level, it is not recommended that such landscape processes are implemented into the assessment at the present time.***

Soil erosion is not generally a significant source of pesticide input to surface waters according to the way that FOCUS Step 3 is parameterised. In agricultural settings subject to excessive soil erosion, various soil management practices such as terracing, contour planting and use of intercropping are frequently implemented to ensure sustainable agricultural production. Due to the management of erosion for the purposes of soil conservation, the transport of pesticides by eroded sediment is generally much less than via runoff except for highly sorptive pesticides.

Based on the list of measures in Table 4, it is possible to establish a realistic level of mitigation that can be achieved for the different routes of exposure. However, there may be concerns over guaranteeing the effectiveness of a particular measure when concerning very high levels of mitigation (e.g. 99% reduction in exposure) for relatively hazardous materials.

Table 4. Listing of mitigation measures suitable for immediate incorporation into ecological risk assessment

Route of exposure	Mitigation measure or mitigating condition	Relative reduction in exposure via route	Implementation into the risk assessment
Spray drift	No-spray (or no-crop) buffer zone	Proportional to extent of drift reduction	Calculate using the FOCUS drift calculator and the FOCUS Step 3 framework
Spray drift	Drift-reducing techniques[a]	25-99%[b]	Calculate using classification systems developed at MS level
Spray drift	Windbreak	25-75% depending on leaf density	Post-processing of output from drift calculator with FOCUS Step 3 framework
Surface runoff	Restriction in the application window	Variable	Calculate using FOCUS Step 3 framework
Surface runoff	Change in application method (e.g. incorporation)	Variable	Refined input to FOCUS Step 3 framework
Surface runoff	Vegetated buffer zone (10-20 m wide)[c]	Variable; reduction in load up to 80% for aqueous and 95% for sediment-bound pesticide (reduction in PEC will be less)	Post-processing of PRZM output within FOCUS Step 3 framework
Surface runoff	Restriction from application to vulnerable situations	Variable	Calculate using FOCUS Step 3 framework and/or refined Step 4 scenarios
Drainflow	Restriction in the application window	Variable	Calculate using FOCUS Step 3 framework
Drainflow	Restriction from application to drained soils	Complete elimination[b]	Calculate using only drift assessment (FOCUS Step 3 framework)
Drainflow	Restriction from application to vulnerable soils	Variable	Calculate using FOCUS Step 3 framework and/or refined Step 4 scenarios
All	Reduction in rate of application	Generally linearly proportional to application rate	Calculate using FOCUS Step 3 framework
All	Change use pattern (crops, timing, etc.)	Variable	Calculate using FOCUS Step 3 framework
All	Change formulation properties	Variable	Calculate using FOCUS Step 3 framework
All	Exposure in rapidly flowing water body	Variable	Calculate using FOCUS Step 3 framework

[a] Techniques considered sufficiently developed are listed in Section 4.4 (Table 6)

[b] Note that maximum reduction that is technically feasible is greater than the maximum cap on mitigation proposed in Table 5

[c] Buffer zone will not be efficacious under saturated conditions

For this reason, it is expedient to set upper limits to the extent of mitigation that can be consider at present based both on technical and political considerations. ***[Recommendation 6] It is recommended that the maximum values identified in Table 5 act as an absolute cap for the incorporation of mitigation into risk assessments for Annex 1 listing (more differentiated maxima can be derived on a case-by-case basis according to the use conditions and options for mitigation).*** The values in Table 5 are intended to be overall maximum possible reductions in exposure. Options are also provided to give reductions in exposure that are less than this maximum (e.g. for mitigation of spray drift). Risk managers will need to decide the applicability and usefulness of particular mitigation measures at the Member State level.

Table 5. Maximum levels of exposure mitigation in risk assessment for Annex 1 listing (note that the largest reductions in exposure may require significant restrictions to the usage area or widespread enforcement of mitigation measures)

Route of exposure	Maximum reduction in exposure recommended for current mitigation approaches
Spray drift	95%[1] (e.g. no-spray buffer or drift reducing technique)
Surface runoff	Variable but not to exceed 90% reduction in PEC (e.g. 20 m vegetated buffer)[2]
Drainflow	90% (e.g. prohibit application to drained soils)[3]

[1] Reductions in exposure of greater than 95% have been obtained using no-spray buffer zones and are also possible based on the most effective drift reduction techniques; EFSA (2006) expresses concern about very large reductions in exposure arising when combining more than one mitigation approach for spray drift. The 95% limit on mitigation at Annex I is proposed to address this concern.

[2] Maximum reductions in the loading of pesticide to water are proposed to be 80 and 95% for compounds transported in the aqueous and sediment phases of surface runoff, respectively. Associated reductions in the volume of water mean that the maximum reduction in exposure concentration will vary on a case-by-case basis.

[3] More completely, the restriction would apply to all soils susceptible to periodic water logging because of slow permeability or rising ground water tables (EFSA, 2006). The connection between upper groundwater and surface water means that the reduction in exposure is difficult to quantify with current tools. The 90% maximum reduction in exposure reflects this fact. A detailed analysis could link predicted concentrations in upper groundwater into the baseflow component within the FOCUS surface water scenarios or use a validated catchment-scale model.

3.4 Risk mitigation for spray drift

The science of mitigation for pesticide exposure via spray drift is better developed than that for exposure via surface runoff or drainflow. Spray drift has been considered as a main route of entry to surface waters within risk assessments both at European level and within national procedures in all Member States surveyed. Many Member States have existing procedures for enforcing mitigation of spray drift during authorisation, although the complexity of the restriction possibilities and the range of mitigation approaches varies significantly.

Three types of mitigation measure are recommended for immediate implementation into the risk assessment. These are the use of no-spray buffer zones, the application of drift-reducing technology and the reduction of exposure using windbreaks. Wind direction and wind speed will significantly affect spray drift, but the potential for control and policing is low so these factors were not considered as viable mitigation options.

No-spray buffer zones are widely implemented at present and have been successfully incorporated into the risk assessment over several years. No-spray buffer zones that have been applied in several Member States over many years are sufficient to provide more than 95% reduction in exposure. Implementation into the risk assessment scheme should continue as at present with the FOCUS drift calculator used to demonstrate the mitigating effect for assessments supporting Annex I listing. For the immediate future, national systems for calculating exposure via spray drift will continue to support authorisations and setting of buffer distances in Member States where separate systems exist. In the medium term, it is desirable to harmonise the different systems and to supplement the FOCUS drift calculator with algorithms for crops and/or application methods that are not currently well covered (see below). Enforcement of the mitigation may be simpler where no-spray buffers are legislated as no-crop buffers, as in the Netherlands.

Technical solutions to reduce spray drift have advanced significantly over the last 10 years. Drift-reducing nozzles are widely adopted by farmers in some Member States and have been incorporated into the risk assessment. It is recommended that the use of this technology is incorporated into risk assessment at the European as well as Member State level. Specific technologies that are recommended for use include drift-reducing nozzles, air assistance, tunnel sprayer, shielded spraying, and band spraying. The application of a particular technique can be considered to cause a relative reduction in deposition of pesticide that is selected as a conservative value from the possible distribution of effects. It should be noted that drift-reducing techniques only need to be implemented for applications made in the area of crop bordering the edge-of-field/water body, since drift interception beyond this point reduces drift to insignificant levels. At the European level, it will only be necessary to stipulate the reduction in exposure via spray drift necessary to reduce risk to acceptable levels. The relevant technology can then be applied at Member State level based on classification systems for drift-reducing techniques which already exist in several Member States (Table 6). This will ensure that the most practicable solutions are implemented accounting for local conditions, application practice and crop systems.

Table 6. Classification systems for drift-reducing technologies

Member State	Location and reference to classification system	Technologies included
Germany	www.bba.de http://www.bba.bund.de/cln_045/nn_807146/DE/Home/pflanzenschutzgeraete/ausgew__veroeff/ausgew__veroeff__node.html__nnn=true	nozzle type air assistance tunnel sprayer sensor sprayer band sprayer hail net
Netherlands	www.ctb-wageningen.nl http://www.ctb.agro.nl/pls/portal/docs/page/website_ctb/beleid_wet_en_regelgeving/01nationale_wet_en_regelgeving/05beleidsregels/070403_driftdoppenlijst.doc http://www.ctb.agro.nl/pls/portal/docs/page/website_ctb/beleid_wet_en_regelgeving/01nationale_wet_en_regelgeving/05beleidsregels/wijziging%20regeling%20driftarme%20doppen_2%20november%202005_stc216.pdf http://www.helpdeskwater.nl/emissiebeheer/landbouw_en_veeteelt/lotv/driftarme_doppen/ http://www.helpdeskwater.nl/emissiebeheer/landbouw_en_veeteelt/lotv/technische_commissie/	nozzle type air assistance shielded boom sprayer tunnel sprayer sprayer boom height band sprayer windbreak net windbreak crop
Sweden	Swedish Environmental Protection Agency (1999). Hjalpreda för bestämning av vindanpassat skyddsavstand [Guide for calculating safety distances based on the wind]. http://www.lrf.se/data/internal/data/01/78/1075729040911/hjalpreda.pdf	nozzle type air assistance shielded boom sprayer sprayer boom height band sprayer
UK	http://www.pesticides.gov.uk/PSD_Databases/products/spray-fp.cfm	nozzle type air assistance shielded boom sprayer

Windbreaks comprising trees or vegetation of at least 1 m higher than the crop have been successfully implemented as a mitigation measure in the Netherlands. Similar approaches are also used in the UK. The approach is suitable for incorporation into ecological risk assessment, but applies only to a windbreak planted immediately adjacent to the water body. The relative reduction in drift deposition can be up to 90% depending on the leaf stage of the windbreak. Recommended values for relative reduction in drift to be used in risk assessment are 25% for bare trees, 50% for trees in intermediate growth stages, and 75% for full (dense) leaf stage. The influence of such measures on the risk assessment could be implemented into the FOCUS drift calculator.

Although mitigation of exposure via spray drift is comparatively well developed, there are several areas where further work is required:

[1] Reference conditions (typical methods) for a particular crop should be established and measurements taken of the normal use pattern so that the drift reduction potential of various techniques can be compared in a standard way.

[2] ISO standards should be adopted to allow harmonisation of approaches for measuring drift and classifying drift reduction.

[3] There are some use patterns and crops that could not be comprehensively covered by the FOCUS drift calculator because of lack of data. New drift data should be generated for these systems or existing data should be collated. As data become available, the current drift calculator in FOCUS should be extended to cover further crop types and mitigation measures for use at Step 4.

[4] Standardised laboratory measurements should be developed for the evaluation of comparative spray reduction (e.g. wind-tunnels, droplet size distributions).

[5] More work is needed to assess the influence of formulation type of the spray solution on spray drift (e.g. the addition of extra adjuvants).

[6] A database of the effectiveness and applicability of spray drift reduction techniques for use in regulatory risk assessments should be created and maintained. This database should be reviewed by an appropriate FOCUS group and considered for inclusion on the FOCUS website.

3.5 Risk mitigation for surface runoff and erosion

3.5.1 Background

In order to consider appropriate mitigation measures for runoff, the potential for runoff entry can be separated into two main components:

1. The portion of pesticide transported in association with particulate, eroded material in the runoff. This is likely to be the major contributor for low solubility, absorptive compounds.

2. The portion of pesticide transported in association with the water phase of the runoff. This is likely to be the major contributor for high solubility, mobile compounds.

For the former case, interception of the transported soil particles will provide the greatest mitigation benefit, whereas for the latter, water transport (and hence infiltration capacity) will be more important. Appropriate mitigation measures for runoff entry should therefore take into account the mobility properties of the compound in question. Wauchope (1978) indicates that transport on the sediment phase will only predominate over that in the aqueous phase for compounds with aqueous solubility of 1 mg/L or less or ionic pesticides with extreme clay-binding capabilities. In experimental studies, Koc is rarely identified as a primary factor for determining buffer efficacy (Reichenberger et al., 2007).

As discussed above, in agricultural settings subject to excessive soil erosion, various soil management practices (such as conservation tillage or contour ploughing) can limit the transport of pesticides by eroded sediment (see for example, www.sowap.org for work on-going in this area). Since pesticide transfer in runoff varies considerably in relation to climatic conditions and numerous local parameters, the effects of mitigation measures in reducing pesticide transport in surface runoff can be variable. This also means that partitioning mitigation measures into strict categories of exposure reduction (e.g. 50, 75, 90, 95%) is more difficult than for spray drift where the variability in influencing factors is smaller. The most effective implementation of mitigation will take place through the application of pesticide management at the local scale, and for Member State registrations, it is important that local climatic, soil and agronomic practices are taken into account when determining suitable levels of mitigation. Nevertheless it is recommended that runoff mitigation approaches can now be broadly implemented into the regulatory risk assessment for Annex I registration in the EU.

3.5.2 *Mitigation Options for Annex I Registrations*

Three mitigation options that are suited to regulatory assessments are:

1. A reduction in the application rate, giving a similar reduction in losses to surface waters via surface runoff or erosion;
2. A restriction in the application window, normally to avoid application during or immediately before periods when the risk of runoff is greatest.
3. The application of a vegetated buffer zone (or filter strip) to intercept runoff water and eroded sediment prior to entry into surface water.

For the first two options, the principles are similar to approaches applied in many Member States to mitigate the risk of leaching to groundwater. Both options should thus be broadly acceptable. The FOCUS surface water scenarios provide a harmonised approach to investigate the impact of the mitigation on pesticide exposure in surface waters. The SWAN software is now freely available to support Step 4 calculations (contact: gerhard.goerlitz@bayercropscience.com). The user can manually enter values for reduction in runoff water, pesticide fluxes and eroded sediment and the system will document the inputs and calculate refined outputs from the FOCUS surface water scenarios.

For the third option, there are already good examples of such approaches being successfully applied at Member State level, where label restrictions are applied to limit runoff input at the point of entry (i.e., next to the water body). For example, in Germany, 5 m and 10 m buffer strips are respectively considered to provide 50% and 90% reduction in runoff inputs (i.e. both water and pesticide load). These measures have been tested in several field studies over recent years and have been found to be effective.

The scientific literature indicates that the main actions of vegetated buffer zones (i.e. those comprised of relatively dense vegetation like grass at the soil surface) in reducing pesticide load transported to surface waters are (1) through an equivalent reduction in the volume of runoff water and (2) through sedimentation of particulate material. The efficacy of vegetated buffer zones depends on many inter-related factors (see Section 1.4.2 of Volume 2) and deriving generalised relationships is difficult at present. Furthermore, the experimental conditions of typical runoff studies may not be directly comparable to those in the field as they tend to be undertaken on small plots, often include artificial rainfall at high intensity and normally only consider sheet flow. The current literature data only apply to situations where: (i) surface runoff enters the buffer as sheet flow (rather than as channelled flow), and (ii) the soil in the buffer is not saturated and the infiltration capacity of the buffer is not reduced by soil surface sealing. A straight-forward analysis of these data is difficult because of the different experimental conditions and the measured variation in buffer efficacy for buffer zones of different sizes. There are also some references where the efficacy of the buffer can only be approximated.

Despite the difficulty of quantifying the runoff reduction efficiency of vegetated buffer zones of a specific size, the view of the majority of the Work Group was that some broad recommendations can be used to guide appropriate mitigation measures to apply to EU Annex I registrations (in the absence of channelled flow, saturated or capped soil). These pragmatic recommendations have been developed with due consideration that the aim of the EU Annex I risk assessment is to demonstrate that a major safe use of the compound in the EU is possible (i.e. not necessarily to be protective of every individual set of circumstances). However, the principles are also applicable at Member State level for national approvals, albeit that more detailed consideration of the local conditions should be applied. In some cases, smaller buffers may be appropriate to achieve the necessary mitigation (as has been demonstrated in Germany, e.g. with 90% reduction for 10-m strips), and elsewhere larger buffers may be required.

Reichenberger et al. (2007) have recently reviewed data on efficiency of vegetated buffer strips in reducing loadings of pesticide in aqueous and sediment phases. A limited amount of additional data have become available subsequent to this review (see Table 1.7, Volume 2). It is difficult to determine whether or not data generated outside of Europe are relevant to European conditions, so an initial screen of the data selected only those results generated in Europe. If the European data are pooled by buffer width and by transport mode (aqueous vs. sediment) then a reasonably consistent pattern emerges. Table 7 provides 90th percentile worst-case values for efficiencies of vegetated buffer zones in reducing the loading of pesticide transported in the aqueous and sediment phases of runoff. The 90th percentile was selected as it has been accepted in analogous cases as providing a sufficient degree of conservatism. The values were calculated assuming a Weibull distribution (cumulative relative frequency = rank/n+1) with linear interpolation between the two measured datapoints surrounding the 90th percentile. Measurements were combined into width intervals (e.g. 18-20 m) to provide a more robust estimate of the 90th percentile. Further information on the statistical analysis is provided in Volume 2, Table 1.10 and associated text. Values for reduction efficiencies proposed in Table 7 below are rounded for ease of use. The efficiency of a given width of vegetated buffer is greater in reducing mass of eroded sediment and associated pesticide than in reducing volume of runoff water and associated mass of pesticide in the aqueous phase.

Table 7. 90th percentile worst-case values for reduction efficiencies for different widths of vegetated buffers and different phases of surface runoff

Buffer width (m)	10-12	18-20
Reduction in volume of runoff water (%)	60	80
Reduction in mass of pesticide transported in aqueous phase (%)	60	80
n (for aqueous phase)	*36*	*30*
Reduction in mass of eroded sediment (%)	85	95
Reduction in mass of pesticide transported in sediment phase (%)	85	95
n (for sediment phase)	*19*	*11*

The values provided in Table 7 are recommended as reasonable worst-case assumptions for efficacy of vegetated buffer zones in good condition. **It should be noted that the reductions apply both to the volume of runoff water and the loading of dissolved-phase or sediment-bound pesticide in that runoff. Thus, for example, a 60% reduction in dissolved pesticide load will result in a significantly smaller reduction in the predicted environmental concentration because the volume of runoff water (and thus part of the dilution capacity) is also reduced by 60%.** The values in Table 7 for reduction in water volume and sediment load are not calculated from measured data, but are set to the same values as for reduction in pesticide load for consistency and ease of use. Variability in the data is greater for narrower buffers (Reichenberger et al., 2007) and for this reason it is not recommended that a buffer of less than 10 m width be considered for Annex I listing. The proposed reduction values represent 90^{th} percentiles from measured distributions; their use in combination with Step 3 exposure values that are themselves realistic worst-case is expected to yield conservative values for use in risk assessment. The possibility for lower or higher efficacy under some conditions cannot be excluded and needs to be considered on a case-by-case basis at Member State level. The availability of experimental data should be considered when determining suitable buffer zones, and values different from those above may be appropriate depending on the results of studies on specific compounds.

3.5.3 Implementation of runoff mitigation into exposure assessment

The reduction in pesticide load for compounds dissolved in runoff results from a corresponding decrease in the volume of water moving as surface runoff. An example of how this relationship can be included into the calculation of predicted environmental concentrations is provided in Section 2.1.2.2 of Volume 2. For some compounds, it may be necessary to consider the fate of pesticide infiltrating into the vegetated buffer zone. It is recommended that appropriate literature citations or experimental data be provided to support the claimed mitigation effect of buffer zones for a specific chemical in recognition of the influence of sorption behaviour on soluble runoff *versus* erosion as key transport mechanisms.

When considering the implementation of runoff mitigation for national authorisations, Member States should also take the following considerations into account. The mitigating effect of buffer zones is reduced or negated for pesticide losses with runoff water when soils become saturated (this does not apply for highly sorptive compounds that are primarily transported with soil particles) or if a significant component of runoff reaches the buffer as concentrated flow. Experimental or literature data should consider these effects. Vegetated buffer zones have been shown to be an efficient measure to reduce soil erosion in agricultural landscapes and are therefore likely to reduce particle-bound pesticide losses to a great extent. It may be necessary to have additional restrictions on use of a pesticide during periods when the buffer is expected to be saturated. At Member State level, the appropriate width of the buffer zone should be defined based on local conditions. For concentrated flow, mitigation measures such as retention ponds should be focused at the point where the runoff enters the water body or buffers should be placed along the line of descent along which concentrated flow collects (buffers in 'cascade').

3.5.4 Research needs

There is a need for further research into the efficacy of vegetated buffer zones in reducing transport of pesticides via surface runoff. The most urgent requirement is for studies investigating the impact of runoff received as channelled flow and of the effect of soil moisture status within the buffer. Further work is also recommended on (i) the fate of pesticide infiltrated in the buffer (e.g. sorption may not reach equilibrium when large volumes of water infiltrate the upper soil layers over short periods) and particularly clarification of the mechanisms for removal of pesticides from runoff and erosion as a function of chemical properties; and (ii) the development of models to simulate in a dynamic way the efficacy of buffers for the removal of pesticides from runoff and erosion. There is little information specific to European conditions on measures such as conservation tillage and conservation landscape management that target control of pesticide transport on eroded sediment. Further work is recommended on these topics.

3.6 Risk mitigation for drainflow

The number of effective mitigation options for reducing exposure via drainflow is limited. This is partly because drainflow has only recently been considered as a primary route of exposure both at Annex I and in many national registration procedures. However, losses via drainflow are also very difficult to control through intervention other than to limit the amount of pesticide applied, the timing of treatment or the types of soil treated.

The only regulatory mitigation options at present are:

1. A reduction in the application rate, giving a similar reduction in losses to surface waters via drainflow;
2. A restriction in the application window, normally to avoid application just before the onset of winter drainage.

Although these options have only been used in practice in two Member States (Germany and the UK), the principles are similar to approaches applied in many Member States to mitigate the risk of leaching to groundwater. Both options should thus be broadly acceptable. The FOCUS surface water scenarios provide a harmonised approach to investigate the impact of the mitigation on pesticide exposure in surface waters.

A number of the mitigation options reviewed in Volume 2 Section 1.5 will be suited to local management of pesticides and/or product stewardship. These include management of soil structure, avoiding application to very dry or very wet soil, and discouraging the practice of "over-draining" (installing more efficient drains than required for a particular soil type). However, none of these approaches is suitable for inclusion in ecological risk assessment as impact on pesticide transport is unpredictable and none can be rigorously controlled or policed.

In the absence of further mitigation based on site management, the only additional option to mitigate risk within ecological risk assessment appears to be a restriction in the soil to which a product may be applied. This could be applied at Member State level according to the level of risk and could take two forms:

1. A blanket restriction from use on any drained land. This mitigation measure is simple to communicate and should, in theory, reduce transport of a pesticide in drainflow to zero. There are areas in Europe where information on whether or not a particular field is drained will not be available. The production of local, fine-resolution maps showing areas likely to be drained under arable cultivation is a potential solution to the problem. EFSA (2006) point out that it is the inherent soil conditions (seasonal water logging within soil layers) that provide the potential for rapid transport of pesticides to surface waters in soils that are frequently drained. Therefore, a more protective blanket restriction would be applied on the basis of soil type, rather than field drainage practice, for example "do not apply to soils susceptible to periodic water logging because of slow permeability or rising ground water tables".

2. A restriction based on soil vulnerability prohibiting use of a product on soils associated with unacceptable risk. Such an approach would be more flexible and it mimics label restrictions imposed by risk managers in the United States. Differentiation of use by soil type is already implemented in Germany and the Netherlands to protect groundwater. A review of European drainage studies (Volume 2, Section 1.5) indicates that there is a relationship between soil type and potential losses of pesticides in drainflow. There are six drainage scenarios with contrasting soil properties associated with FOCUS surface water step 3. These provide a harmonised modelling framework which could be extrapolated using the maps and summary statistics in the FOCUS SWS report.

4 INCORPORATING MODELLING REFINEMENTS AND MITIGATION INTO EXPOSURE ASSESSMENT AT STEP 4

4.1 Introduction

The FOCUS Surface Water Scenarios Working Group has implemented three sequential steps for modelling aquatic exposure to pesticides:

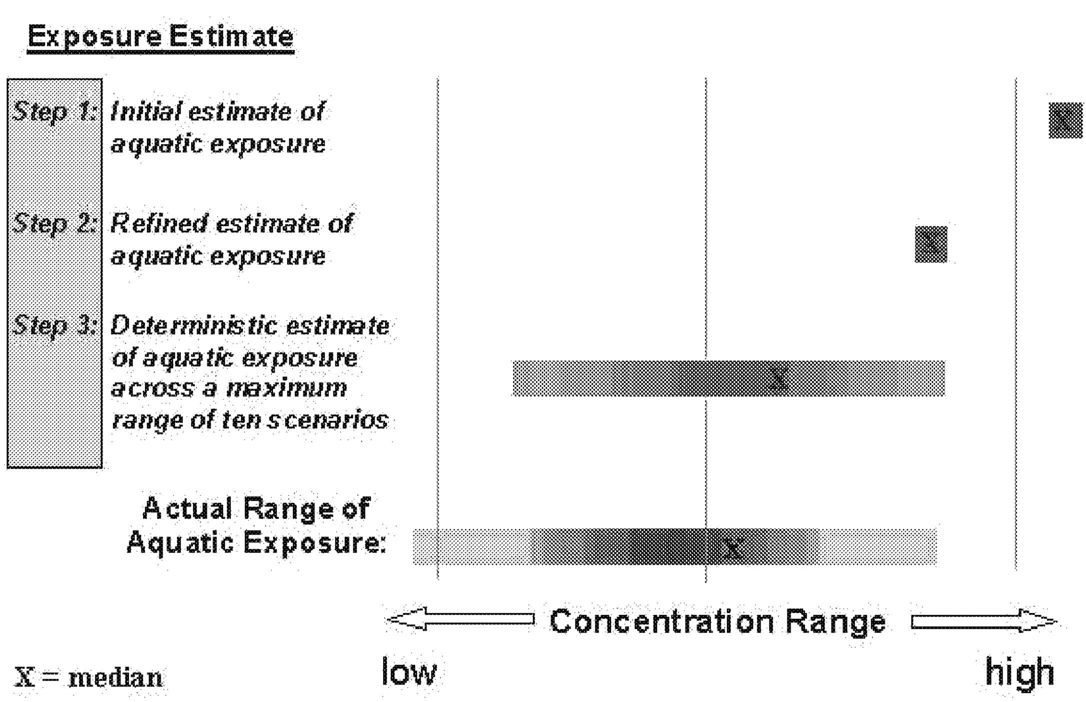
Step 1: a simple spreadsheet calculation intended to provide conservative aquatic concentration estimates, somewhat higher than would actually be observed;

Step 2: a refined spreadsheet calculation intended to represent the high end of actual aquatic exposures;

Step 3: mechanistic modelling of drift, drainage, runoff and erosion coupled with aquatic fate for scenarios designed to capture a range of realistic worst-case conditions for the European agricultural area.

This sequence of steps is represented schematically in Figure 2. Higher-tier exposure assessments are conducted at Step 4.

Figure 2. Conceptual relationship of FOCUS Steps 1, 2 and 3



Step 1 and 2 calculations include a number of conservative, simplifying assumptions, such as assuming 2-10% instantaneous aquatic loading from runoff or drainage as well as assuming a single set of fixed dimensions for the receiving water body. Such assumptions make it possible to determine an initial concentration in a water body using simple algebraic equations. However, due to the conservative nature of these assumptions, the estimated concentrations from Step 1 and 2 are likely to be higher than or at the very top end of the distribution of actual environmental concentrations. In practice, the Step 1-2 Calculator is likely to provide PECsw values leading to acceptable risk for compounds with minimal aquatic toxicity as well as for metabolites with low aquatic toxicity.

The more mechanistic calculations performed at Step 3 are an attempt to generate realistic worst-case aquatic concentrations (as defined by the FOCUS Surface Water Scenarios work group). However, it should be recognised that even Step 3 calculations include a number of conservative assumptions, such as the use of minimal buffer zones between crop and water for evaluation of spray drift and delivery of edge-of-field runoff directly into surface water. As a result of these assumptions, the predicted concentrations are towards the top end of the distribution of concentrations that would be observed across the usage area and thus these scenarios are assumed to generate "reasonable worst-case" aquatic concentrations.

The goal of performing Step 4 surface water modelling is either to provide a more accurate estimate of exposure concentration likely under actual usage conditions or to evaluate the influence on exposure of one or more mitigation options. The proposed refinements can be divided into three types of change:

1. Relatively straightforward changes to individual model parameters to alter chemical properties, application rates or dates or specific environmental parameters influencing the loadings from drift, drainage or runoff or the hydrology of the water bodies;

2. Changes to the modelling to incorporate the use of a risk mitigation measure;

3. More complex refinements that might involve creation of new scenarios, use of chemical monitoring data or the application of probabilistic approaches or distributed catchment models.

Clearly, changes to the modelling should be based on the problem formulation (Section 3.1) and thus focus on the most important factors for exposure. The approaches to refine aquatic exposure assessments are discussed in turn below.

4.2 Incorporating refinements and mitigation based on existing FOCUS scenarios

The first approach to be considered in refining the exposure assessment should be making changes to parameters within existing FOCUS Step 3 scenarios. Changes that may be made include re-examination and/or refinement of chemical parameters, changes to model parameters describing the scenario, and incorporating the effect on exposure of a mitigation measure. A distinction is made between refinement which here means increasing the realism of the description of the chemical or the scenario, and mitigation which here implies that the scenario is adequately realistic and that an identified risk needs to be reduced by imposing some form of use restriction. General principles for these changes are discussed below and examples that might be made are listed and classified in Table 8.

Refinement of the existing scenarios has to be fully justified and presented in a transparent manner. It is desirable that guidance should be developed on how to report changes to the modelling so that it is clear to the reviewers what steps have been taken and why. ***[Recommendation 7] Any change to the Step 3 scenarios is considered to be a Step 4 calculation and this should be clearly stated in the monograph.***

Development of software tools to support Step 4 calculations was outside the scope of the working group. Independent work has been undertaken by ECPA to develop a modelling tool called SWAN. The software operates within the framework of the existing FOCUS surface water scenarios and supports Step 4 calculations through changes to input files for PRZM, FOCUS and TOXSWA. For example, the system allows the user to incorporate mitigation of spray drift or surface runoff or to add in exposure via air where this is known to be a significant route of environmental exposure. SWAN is freely available to users (contact: gerhard.goerlitz@bayercropscience.com).

4.2.1 Refinement of input parameters for the chemical

The current FOCUS guidance is to use mean or median values for environmental fate parameters of the parent and its degradation products. New guidance is being developed by the FOCUS Degradation Kinetics group on calculating the most appropriate values from laboratory and field studies and on averaging the results of these studies using the geometric mean for subsequent modelling. Any refinements at Step 4 should be within the context of this guidance.

Additional environmental fate studies may be needed to adequately represent the runoff, drainage and aquatic fate of some chemicals. Examples of refined environmental fate studies include rate of degradation on plant foliage, rate of washoff from foliage, rate of degradation in an irradiated water/sediment study, bioavailability of soil residues and volatility from soil and water. Many of the results from refined environmental fate studies can be used directly as a refinement to Step 3 modelling. There is a requirement for additional work to develop international test guidelines for several of these studies.

4.2.2 Refinement of input parameters for the scenario

The availability of landscape level data allows the refinement of Step 3 scenario parameters by providing more realistic/appropriate data for re-running Step 3 models at Step 4. The level of confidence likely to be assigned to particular parameters derived using landscape analysis is described in Section 6.3.

Certain parameters that can readily be refined have already been identified by FOCUS (2002; e.g. the width of the buffer zone between crop and water, the size of the upstream catchment and specification of the site-specific soil characteristics). Refinement of the existing Step 3 scenarios can be done by providing justification for adjusting one or more key model input parameters that will result in improving the realism of the calculations. Detailed information on a wide range of modelling inputs that are subject to refinement is listed in Volume 2, Section 2.1.2. The upstream catchment, its cropping and pesticide use are all highly simplified within the Step 3 scenarios. Modification of the assumptions may be a simple refinement at Step 4 where they are shown to deviate markedly from reality (e.g. for applications to specialised crops). EFSA (2006) suggest that such changes may be better accommodated within the more realistic framework of catchment-scale modelling (see Section 4.3.3). It may be appropriate to refine the timestep for modelling (e.g. using hourly weather data) to simulate highly dynamic processes such as preferential flow.

Some of the model and scenario inputs can be refined through the use of spatial analysis of key agricultural areas within Europe, providing assessments of, for example, geographic distribution of a specific crop, associations of crop and soil types, proximity of crop and water and cropping intensity within a catchment. Landscape analysis of selected regions within Europe provides an independent means of refining spatially-based parameters such as buffer width and percent area cropped which have been set to fixed values for use within Step 3. Additional details of specific landscape-based refinements are provided in Volume 2, Section 2.1.2.

4.2.3 Simulation of mitigation measures

Aquatic exposure assessment at FOCUS Step 3 is relatively complex and often combines exposure via multiple routes of entry (e.g. spray drift plus either runoff or drainflow). ***[Recommendation 8] To support any proposal for exposure mitigation, it is appropriate to demonstrate the potential effect of the mitigation through the use of refined Step 4 modelling.*** The current Step 3 models can readily be modified to provide reasonable estimates of mitigation measures such as drift reduction, effects of buffer width on runoff and erosion as well as the effects of altering application rates and/or timing; this may sometimes be achieved through the use of empirical factors derived from measured data. More complex mitigation measures may require additional modelling effort to characterise the effects. In some cases, it is likely that development of new scenarios may be necessary to address uses not covered by the FOCUS Surface Water Scenarios. As modelling becomes more complex, the suite of models used at Step 3 may reach their bounds of applicability. The validation status of the models should be carefully considered. In some cases, it may be appropriate to support the calculated refinements with experimental data that might, for example, allow a calibration step or be used to demonstrate the reliability of model predictions.

Risk mitigation measures that are considered sufficiently developed for immediate inclusion into European registration procedures are identified in Table 4. The ability to simulate the influence of the measure on exposure and thus on risk was one of the criteria for deciding on the status of individual measures. Table 4 also identifies the approach to demonstrate the efficacy of the mitigation measure.

Two of the obvious ways to reduce predicted aquatic concentrations is to reduce the application rates of the applied chemical or change the pattern of use. Acceptable TER values for aquatic organisms can sometimes be obtained by simply reducing the number of applications and/or individual application rates (note that the need to maintain efficacy is a clear prerequisite for such an approach).

Another feature of chemical applications that can strongly influence aquatic exposure potential is the timing of the applications. In many regions of Europe, autumn and winter applications generate larger concentrations in drainage systems as well as runoff due to the greater amounts of precipitation coupled with cooler temperatures that commonly occur during the autumn and winter seasons. For some chemicals, autumn applications may pose a significantly higher exposure to aquatic organisms than spring/summer applications, requiring modification of autumn use rates and possible restriction of autumn/winter application windows in order to achieve aquatic safety.

In the case of other commonly applied mitigation strategies such as buffer zones, it is essential to provide supporting evidence of the efficacy of buffer zones from appropriate field studies or existing regulatory guidance. Detailed information on the Step 3 parameters subject to Step 4 refinement is provided in Volume 2 Section 2.1.2 together with information on potential sources of data to support the proposed changes. As summarised in Table 8, these changes include refinements in chemical properties, application rates and timing, agronomic characteristics, aquatic loadings via drift, runoff and drainage and aquatic fate. Simple refinements can be implemented within the current FOCUS Step 3 framework, whereas complex refinements need substantial additional work.

Table 8. Examples of relatively simple changes to modelling at Step 4 to increase the realism of the simulation or include the influence of a mitigation measure

Exposure component	Type of modification	Factor	Amenable to landscape analysis
Drift/runoff/drainflow	Mitigation	Application rate	-
	Mitigation	Application timing / frequency	-
Runoff/drainflow/ aquatic fate	Chemical refinement	Chemical parameters	-
Runoff/drainflow	Scenario refinement	Probability of occurrence and intensity of event-driving rainfall and of antecedent moisture conditions	Yes
Drift	Simple scenario refinement	Drift values	-
	Complex scenario refinement	Distribution of natural margin distances between crop and surface water	Yes
	Complex scenario refinement	Interception by bankside vegetation	Yes
	Complex scenario refinement	Wind direction	Yes
	Mitigation	Influence of no-spray (or no-crop) buffer	-
	Mitigation	Influence of drift-reducing technology	-
	Mitigation	Influence of windbreak	-
Runoff/drainflow	Complex scenario refinement	Irrigation method and schedule	-
	Simple scenario refinement	Cropping dates or parameters	
	Simple scenario refinement	Soil profile properties	Yes
	Simple scenario refinement	Simulation year	-
	Complex scenario refinement	Spatial distribution of treated fields in catchment	Yes
	Mitigation	Formulation / application method	-
Runoff	Mitigation	Pesticide retention in buffer zone	Yes
Loadings to surface water	Complex scenario refinement	Upstream feeding area	Yes
	Complex scenario refinement	Proportion of catchment treated	Yes
	Complex scenario refinement	Timing of catchment hydrograph	-
Aquatic fate	Complex scenario refinement	Dimensions of the water body	Yes
	Complex scenario refinement	Hydrology (e.g. weirs for ditches and streams, lack of seepage for ponds, baseflow assumptions)	-
	Simple scenario refinement	Influence of macrophytes on fate and retention of pesticides	-

A more detailed summary of initial refinements of Step 3 scenarios is given in Volume 2 Section 2.1.2.

4.3 Step 4 exposure assessment outside of the FOCUS scenarios

The FOCUS Step 3 framework for fate modelling imposes restrictions on exposure assessment because of the scale, the limited number of scenarios and/or models, or the deterministic nature of the process. It will therefore sometimes be appropriate to move outside of the FOCUS Step 3 scenarios at Step 4.

4.3.1 Development of new scenarios

The FOCUS scenarios were selected to be representative for large areas of the EU and for major crop types. However, it is recognised that the ten Step 3 scenarios cannot encompass the full range of conditions for some crops and specialist cultures and that it may be necessary to develop additional scenarios to support Step 4 calculations. Equally, the scenarios may not represent typical running waters (in that they may underestimate potential dilution factors), larger ponds or areas where there is very little surface water. When developing new scenarios, the scale of the assessment should be carefully considered to capture the major environmental and agronomic influences on exposure. ***[Recommendation 9] It is strongly recommended that the location of additional scenarios should follow the procedures for overlaying data (i.e. soil, climate, slope, cropping) outlined by the FOCUS surface water scenarios group.*** A possible approach is given as as Appendix 1 to this report. It should be noted that the approach is not intended to be prescriptive and that the PPR panel have critiqued the methodology and put forward an alternative approach (PPR, 2006).

Landscape analysis has a significant role in deriving scenarios that are representative and in being able to extrapolate results to the wider area of use. These issues are discussed in Sections 6.2 and 6.5.

It would be highly desirable for the Step 3 scenarios to be updated over time to account for improved availability of data (e.g. to ensure continuity with Step 4 calculations for specialised cultures). At a suitable point in time, additional scenarios developed to support Step 4 could be passed into a FOCUS Group for review and consideration for inclusion in a future revision of FOCUS Step 3.

4.3.2 Probabilistic modelling

In real world settings, both exposure and effects are highly variable in space and time due to chemical use patterns, environmental characteristics and biological attributes. Therefore, it is often informative to broaden the representation of toxicity and exposure values from single "reasonable worst-case" values to distributions of values. In addition, there are uncertainties associated with inputs and outcomes of the risk assessment. Probabilistic approaches can be used to quantify and express variability and/or uncertainty associated with the risk assessment. Quantification of uncertainties to provide confidence intervals around estimates of risk provides greater information to the risk manager. Formal listing of uncertainties that have not been quantified and a qualitative analysis of their likely impact on the assessment have been recommended (EFSA, 2006). The advantages and disadvantages of probabilistic approaches for probabilistic risk assessment of pesticides have been extensively discussed and have been summarised as follows (Hart, 2001):

Advantages of probabilistic risk assessment:

- it helps to quantify variability and uncertainty;
- it can produce outputs with more ecological meaning (e.g. probability and magnitude of effects);
- the method makes better use of all available data;
- the method identifies the most significant factors contributing to risk
- it can provide an alternative to field testing or helps focus on key uncertainties for further study in the field
- the method promotes better science by considering multiple possibilities

Disadvantages of probabilistic risk assessment:

- the analysis is more complex;
- it may require more data;
- the results may be difficult to communicate;
- the method can potentially lead to misleading results;
- there is at present no agreement on what outputs are required or how to interpret them;
- validation is difficult.

For the foreseeable future, deterministic methods are likely to remain the primary tool for lower tiers of risk assessment. Probabilistic methods are one of the tools available at Step 4 and they should be used together with other lines of evidence to improve the understanding of exposure, toxicity and resulting risk. As a generic technique, probabilistic methods will have application in refined exposure assessment based on FOCUS Step 3 scenarios (Section 5.2) and in assessments outside of the FOCUS scenarios (Section 5.3). The approach particularly lends itself to use in conjunction with the output from landscape analysis. As well as providing information on the variability in input parameters, landscape analysis may have a role in assessing spatial variability in exposure concentrations during validation of probabilistic calculations. The extent to which areas of high risk are aggregated into 'hot-spots' should be one of the outputs of any spatial analysis. Results may have applications in prioritising further work or targeting mitigation requirements. ***[Recommendation 10] It is recommended that probabilistic methods can be applied as one of the approaches to refining assessments of exposure and/or effects at Step 4 and that this conclusion is equally applicable for the aquatic and terrestrial compartments and for fate and/or effects componenents. Probabilistic assessments should only be accepted when they are conducted in an appropriate manner; further details of the main considerations will be made available in the final report of the EUFRAM project (www.eufram.com) which is expected to be published in summer 2007. It is further recommended to follow the US EPA's general guidance on criteria for acceptance of Monte Carlo assessments (US EPA, 1997)***

Step 3 exposure assessment is based on simulations for a single year, albeit that the year for which results are reported is selected based on output from 20-year simulations. Surface water exposure may be significantly influenced by individual storm events for which the pattern varies greatly from year to year. A simple example of a probabilistic output would be to run the exposure assessment for multiple years in order to examine the variability in exposure over long time courses. This step mirrors the approach in generating predicted environmental concentrations for groundwater according to FOCUS recommendations where long-term (20, 40 or 60 year) simulations are undertaken and the 80^{th} percentile annual concentration used for the risk assessment (FOCUS, 1999). This is only an example of a simple refinement based on probabilistic assessment. In any probabilistic assessment, those parameters which remain deterministic should be fixed to appropriate values, which are selected so as to achieve an appropriate overall degree of conservatism in the results.

A significant amount of information on the development and use of probabilistic modelling for higher-tier risk assessments as well as recommendations for interpreting and applying the results of probabilistic assessments is available (e.g. ECOFRAM, 1999; Dubus et al. 2002; 2003). The EUFRAM project is supported by the European Commission's 5th Framework Programme and aims to improve the use of probabilistic approaches for assessing the environmental risks of pesticides. The project deliverables include a framework of guidance for risk assessors, end-user training and networking with stakeholder groups. The project is due to report in summer 2007and details can be found at www.eufram.com. Probabilistic approaches have not been reviewed by the FOCUS Landscape and Mitigation Work Group as EUFRAM is fully addressing the role of these techniques within risk assessment for pesticides.

4.3.3 Catchment-scale modelling

The FOCUS surface water scenarios simplify the properties of a catchment down to a single soil column with one crop, one set of weather conditions and one lower boundary condition. Catchment models are designed to capture more of the variation within a catchment than a single column will reveal, meaning that some areas will be less vulnerable to leaching, runoff or drift and others may be more vulnerable than found at Step 3. Climate, vegetation and soil properties are distributed over the catchment, and it is possible to distribute input such as location of fields, time of spraying and spray drift. Spray drift could, for example, be modified according to occurrence of natural buffer zones in the landscape and exposure of the water body due to wind direction (i.e. the wind is not always blowing towards the water body). A catchment modelling approach to simulation of surface runoff and erosion is clearly advantageous, as single column models are unable to describe changes in topography and vegetation.

Catchment models differ in complexity in the description of different hydrological compartments (see Table 2.1.3 in Volume 2). For example, the computational units of erosion models may be planes and channels, or uniform grids. Groundwater may be simulated by linear reservoirs or fully discretised in three dimensions (only the last method provides enough detail to deal with solute transport in surface water). Very importantly, the varying conditions with respect to the lower boundary of the soil columns are dealt with. As the upper part of the groundwater model produces the boundary condition for the columns above, the conditions are influenced by the general topography. Water runs horizontally between grid points in the groundwater model, and may accumulate in lower areas. This particular factor leads to considerable difference in macropore flow between different root zone columns, as macropore flow is induced more often in the wetter areas. Drainage is also selectively activated according to where the groundwater or perched water table rises above drain level. Drainage from perched water tables in clay soils may exacerbate transport of particulates to surface water.

Distributed modelling and catchment models have been used for a considerable time in the field of hydrology. The first examples of catchment models designed for use in pesticide risk assessment are just beginning to appear. The Danish EPA has funded production of a catchment model for pesticide registration purposes. The final product of the project ”Pesticides in Surface Water” is a model tool (PestSurf) that can be used in the registration procedure for new pesticides (Styczen et al., 2004). PestSurf is based on models of two existing catchments.

As with several of the methodologies considered by the working group, the review of the science indicates that catchment modelling for pesticide risk assessment is in its infancy. ***[Recommendation 11] The group does not recommend routine inclusion of catchment modelling into ecological risk assessment to support Annex I listing. The development of validated catchment modeling approaches, linked to Step 3 scenarios should be addressed as a priority to support European level regulation and catchment monitoring requirements (e.g. those of the Water Framework Directive).*** It is uncertain how output from catchment models should be used for the evaluation of effects; for example, what are the implications if toxicity values are exceeded in only a small part of the stream system for a limited time? Should concentrations generated in small tributaries with only a few cm of temporary water be evaluated in the same way as concentrations in permanent water bodies? Nevertheless, several recommendations are made on the use of catchment models:

[1] As catchment modelling attempts to mimic reality, the model results should be comparable to monitoring data provided that these represent the agricultural practices modelled (and not point sources). The model thus provides a means of testing process descriptions and their interactions at the catchment level, an issue that is not well described at present. This type of modelling can serve as a test of simulations undertaken at higher tiers.

[2] The uncertainties and complexities associated with distributed catchment modelling make it essential that monitoring data are available for calibration and/or demonstration of predictive ability.

[3] Point source contamination makes comparison between model output and chemical monitoring data difficult. Separation of point and diffuse contamination should be one of the key aims in generating monitoring data for model evaluation.

[4] Work is required to further develop catchment modelling approaches suitable for application within risk assessment for pesticides.

Catchment-scale assessments may be appropriate at Member State or regional level where data have been generated specifically to validate the approach (e.g. scenario-based exposure modelling with PESTSURF in Denmark). It will be appropriate to reconsider the utility of catchment models for European risk assessment at a later date. Developments in the area will be driven by any move to predict concentrations for drinking water abstraction, although it should be recognised that the risk assessments for drinking water and ecology have quite different requirements.

4.3.4 Use of chemical monitoring data

There are significant surface water monitoring programmes in place throughout Europe that are designed to pick up prominent pesticides (further information on the state-of-the-art is provided by EFSA, 2006; Section 3.3.4). Monitoring has the possibility of being a very useful 'reality check' on exposure predictions but can be difficult to interpret because of a wide range of uncertainties. These include:

1. Sampling constraints – what is the spatial and temporal resolution of the data and how does this relate to pattern of use in space and time?

2. Representativeness – monitoring data are often collected from large streams, rivers and lakes and this limits their application in risk assessment focusing on exposure in ditches, small streams and ponds.

3. Influence of point source contamination – numerous studies have shown that point sources can account for a significant part of the total contamination of larger water bodies by pesticides; again this limits application within a risk assessment considering only contamination arising from good agricultural practice.

[Recommendation 12] Appropriate monitoring data for example compounds can provide support for refined or higher-tier risk assessments (e.g. landscape assessments, catchment modelling, probabilistic techniques). Design of the monitoring approach would need to consider non-diffuse sources of entry to surface waters. The need to establish a causal relationship between use and occurrence in water dictates that highly specific monitoring will be required. Monitoring is normally a post-registration procedure, but where monitoring is possible then data meeting all quality criteria and collected at the appropriate temporal and spatial resolution should be given a prominent position in the tiered assessment.

As monitoring data become available, it would be useful to compare these with the values generated by the FOCUS surface water tools. The comparison of FOCUS Step 3 results with chemical monitoring data is not straight-forward because of the broad, representative nature of the scenarios. Monitoring data should be compared to model results from runs that are parameterised to the local conditions.

5 METHODS AND DATA FOR DESCRIBING AGRICULTURAL LANDSCAPES

5.1 Introduction

Over the last decade, there have been substantial developments in the methods and data that are available for quantitatively describing the agricultural landscape. Technical advances and availability of remote sensing data (both from satellite and aerial imaging) for measuring land-use, land-cover (LU/LC) and accessibility to digital geographical datasets (e.g. hydrology, slopes, soils, etc) means that analyses covering large areas of land are increasingly feasible. Many of these analyses are being implemented via the use of geographical information systems (GIS) that enable the spatial processing of such large data sets. GIS are a collection of tools that can be used in many and varied ways to provide an analysis of the landscape. The availability of landscape level data allows the refinement of Step 3 parameters by providing more realistic/appropriate data for re-running Step 3 models at Step 4. In addition, appropriate use of landscape data can also provide supplementary information for exposure assessment that is not directly tied to specific model parameters, yet may help to gain a broader understanding of exposure in the landscape to address specific issues arising from Step 3 modelling. Finally, landscape analysis is an integral part of Step 4 assessment outside of the current Step 3 scenarios, as landscape level information may be required for the development of new scenarios, probabilistic modelling, and catchment-scale modelling.

As part of its remit, the Work Group was asked to review the science base for landscape analyses and the potential for implementation in Step 4 exposure assessments. This chapter provides a summary of the findings and recommendations of the Landscape Analysis Subgroup. The chapter deals principally with the methods and data applicable for characterizing the agricultural landscape. Further information on the use of such data to refine models at Step 4 is included in Chapter 2 of Volume 2. While attempts have been made to compile a broad cross-section of spatial approaches, the scope of this task is large, and the reader should also refer to the literature and ongoing conference proceedings for information on additional approaches.

5.2 Problem formulation, site selection and units of analysis

As with all components of higher-tier risk assessments, developing a suitable problem formulation is a crucial step (see Section 3.1). The appropriateness of the data and/or approaches used will depend on the objective of the risk assessment. ***[Recommendation 13] When using landscape analysis to support higher-tier assessments, a full justification should be provided for the approach used to generate and analyse data and of subsequent use in modelling.***

The process of selecting an appropriate area for examination is crucial to the understanding, interpretation, and scope of the results of that examination. This "site selection" process should be considered carefully prior to the initiation of any specific analyses at the landscape level.. The aim of the site selection is to pick an area/region for study that is consistent with the objectives of the risk assessment. This process will normally begin at the EU level, with refinements progressing through national, regional and local considerations. An example of how such a process would be conducted is included in Appendix 4 of this report (Valencia, citrus example). ***[Recommendation 14] The rationale and justification for the site selection should be thoroughly documented.***

An inherent part of the problem formulation step is to decide upon the 'unit of analysis' for use in the study. The unit of analysis is that spatial feature to be examined as either a contributor or receiver of potential exposure. For surface water risk assessments, this could be either the water body (as that unit receiving potential exposure and which should be evaluated), or the agricultural field (as that unit contributing potential exposure, with possible mitigation). Other approaches include the analysis of catchment areas, grid cells, and even individual water body segments. For drift studies, the units may be defined mainly on parameters such as distance and size, while for runoff and drainage, factors affecting the hydrology will be more important for the definition of appropriate units. A variety of approaches are valid/appropriate for specific purposes, and all should be considered for the specific application. Data requirements and availability, scale, level of GIS complexity and processing time required are all considerations that should be taken into account. Further details concerning approaches to the various units of analysis can be found in Volume 2, Section 2.3.1.

5.3 Refining Step 3 model parameters using landscape information

The appropriate landscape factors to assess will depend on the issues identified in the problem formulation phase. A range of landscape factors can be used in the refinement of an exposure assessment. Examples are summarised in Table 9 and Table 10 below, together with an estimate of the level of confidence, complexity and data availability for conducting the analysis.

Table 9. Example landscape factors with potential for use in refining the exposure assessment at the field scale

Exposure component	Modelling parameter	Landscape factor	Data availability[a]	Ease of preparation[b]	Applicability to exposure assessment[c]
All	Cropping density	Cropping density	Medium	High	High
Drift	Buffer width	Buffer width / crop-water body distance	Medium	Medium	High
Drift	Mitigation of no-spray buffer	Crop-water body distance imposing a no-spray zone	Medium	Medium	High
Drift	Interception	Buffer composition – filter effect of intervening vegetation	Medium	Medium	High
Drift	Wind direction	Wind direction	Medium	Medium	Medium
Drift	Wind speed	Wind speed	Medium	Medium	Low
Drift	Mitigation of no-spray buffer	Filter effect of intervening crop	Medium	Medium	Low
Runoff	Soil properties	Soil properties under crop, or between crop & water	Medium	Medium	High
Runoff	Climate	Weather data	Medium	Medium	High
Runoff	Buffer width	Buffer width / crop-water body distance	Medium	Medium	Medium
Runoff	Interception	Buffer composition – filter effect of intervening vegetation	Medium	Medium	Medium
Runoff	Slope	Elevation / Slope	Medium	Medium	Medium
Runoff	Land management factor	Land management practice	Low	Medium	Medium
Drainage	Climate	Weather data	Medium	Medium	High
Drainage	Soil properties	Soil properties under crop	Medium	Medium	High
Drainage	Drainage density	Presence and density of drain tile	Low	Medium	High
Loadings to surface water from upstream	Proportion of catchment cropped	Cropping density	Medium	High	High
Loadings to surface water from upstream	Upstream feeding area	Catchment area	Medium	Medium	Medium
Loadings to surface water from upstream	Proportion of crop treated	Proportion of crop treated at a single point in time (application window)	Low	Medium	Medium
Aquatic system	Water body dimensions	Distribution of water body types / sizes	Low	High	High
Aquatic system	Hydrology	Flow, dilution, permanence	Low	Low	High
Aquatic system	Ecology	Interception (filter) and adsorbtion effects of macrophytes	Low	Low	Medium

[a, b, c] For key see below Table 10

Table 10. Example landscape factors used as supporting information for higher tier exposure assessment

Landscape Factor	Supporting information	Data availability[a]	Ease of preparation[b]	Applicability to exposure assessment[c]
Cropping density	Describes overall cropping density and distribution	High	High	High
Surface water characterisation	Describes overall water body types and distribution	Low	High	High
Potentially exposed water bodies	Describes the proportion of all water bodies that may potentially be exposed to crop within a specific distance	Medium	High	High
Amount of crop that does not expose surface water	Describes the amount of the total cropped area that is located beyond a specific distance from water	Medium	High	High
Crop variation	Describes the variability in crops (level of monoculture), to assess the potential for simultaneous treatment	Low	Medium	Medium
Field size variation	Infer the potential for crop homogeneity from field size, as well as potential for simultaneous treatment	Medium	High	Low
Spatial distribution of potential exposure	Describes the relative exposure of lesser and greater areas/catchments/water bodies to show density of exposure and potential for mitigating effects and ecological relevance (dilution, re-colonisation, etc.)	Medium	Medium	High

a Data availability: A summary of data availability, accessibility, cost for these types of data in general across the EU. More readily available or detailed data sets may be available for certain regions or Member States.

b Ease of preparation: A summary of the level of complexity/processing, combined with appropriate knowledge, to generate the relevant modelling parameters from source data.

c Applicability to exposure assessment: An overall judgment on the applicability of utilizing spatial data to generate relevant landscape factors for improving exposure assessment at the field scale. This column is not meant to describe the relative significance of the modelling parameter to final exposure estimates.

The tables above (and the corresponding text in Section 2.3 of Volume 2) present a general overview of the types of landscape factors that can be applied to Step 4 modelling, but do not stipulate that specific data sets or methods be used. Since the use of landscape-level information at Step 4 is currently a rapidly evolving process, a single set of metrics and methodologies cannot be presented as a definitive set of FOCUS approved approaches. ***[Recommendation 15] For complete understanding and transparency, when GIS and landscape-level information are used at Step 4, a thorough description of the GIS data, processing and methodology should be presented in the report so that the reader can properly evaluate the process and the results.*** A recommendation for research requirements

(Chapter 8 of this document) proposes that a future work group develop more defined guidelines for the appropriate use/scale of spatial data, spatial processing of the landscape data, and suggested methods to be used for generation of landscape factors and exposure estimates. The aim of this is to promote consistency in future exposure assessments that utilise landscape-level information.

5.4 Data Availability

One of the current issues with implementing a proper site selection process and developing refined landscape factors for Step 4 analyses is that pan-EU data are not readily available for certain crucial data layers (e.g. climate and hydrology). While Member State level data sets do exist in many cases, lack of consistency, scale and content preclude the use of a combined version of these data sets for most trans-EU applications. A discussion of existing EU-wide data sets is included in Volume 2, Section 2.4, while a non-exhaustive list of national level data sources compiled for the FOCUS process can be found at http://viso.ei.jrc.it/focus. Please note that data sources and available data sets change over time, and the list presented represents only a portion of the currently available information. It should be used as a starting point for more detailed data research.

5.5 Relating a landscape analysis to a larger area (context setting)

It is important to understand how an analysis of a particular agricultural landscape (selected for specific crop, environmental or other factors) relates to the broader EU context, particularly if such an analysis is used in the Annex 1 registration process to demonstrate a safe use. While the scenarios selected by the FOCUS Surface Water Scenarios workgroup are representative of large areas of the EU, the parameterisation of the scenarios uses some broad characterisations of parameters. If these parameters are refined based on landscape-level spatial information, it is critical to be able to place the refined spatial information (and derived results) into a broader context. ***[Recommendation 16] If not well documented in the site selection process, an appropriate EU-wide examination should be conducted to set the results for the site/region that has been examined into a broader context***. Several methods have been developed to conduct this type of analysis (see Volume 2, Section 2.3.5), and the majority of data sets are also available, with some caveats (e.g. hydrology, climate and soil data at appropriate scales).

5.6 Other General Discussion Points

In order to provide confidence in the results of landscape-level studies, some selected monitoring (chemical and/or biological) may be needed to confirm the risk assessment (e.g. with example compounds). Such studies would also need to consider non-diffuse source entry.

One advantage of the landscape analysis approach is that it can produce distributions of factors contributing to exposure (e.g. soil properties, buffer widths, cropping density, etc.) and distributions of potential exposure concentrations estimated for the unit of analysis (e.g. water body, catchment area, etc.). This clearly has potential applications in probabilistic risk assessment.

Landscape analysis and spatial tools are important for catchment-scale modelling in order to characterise catchments (and their variability) for potential exposure factors.

Landscape analysis also allows the development of maps of potential risk (or exposure), i.e. maps that show the spatial distribution of concentration (measured, predicted or a combination of the two), allowing potential 'hot-spots' to be identified. This approach may have applications in the development of spatially-differentiated mitigation approaches in the future, as well as the ability to spatially relate areas of greater/lesser exposure to ecological information to better understand potential risk in the agricultural landscape.

A landscape analysis allows the description of factors that influence exposure that are not currently included in the Step 3 models (e.g. variability of exposure within a water body, directional component of drift, etc.). It may be possible to build these factors into the models in the future as additional landscape analyses are conducted. Recent efforts in this area have focused on refining spray drift inputs. Future work should put more emphasis on input refinement and ways to include parameter variation into estimates of exposure via drainage and runoff.

6 ECOLOGICAL CONSIDERATIONS IN LANDSCAPE ASSESSMENTS

6.1 Introduction

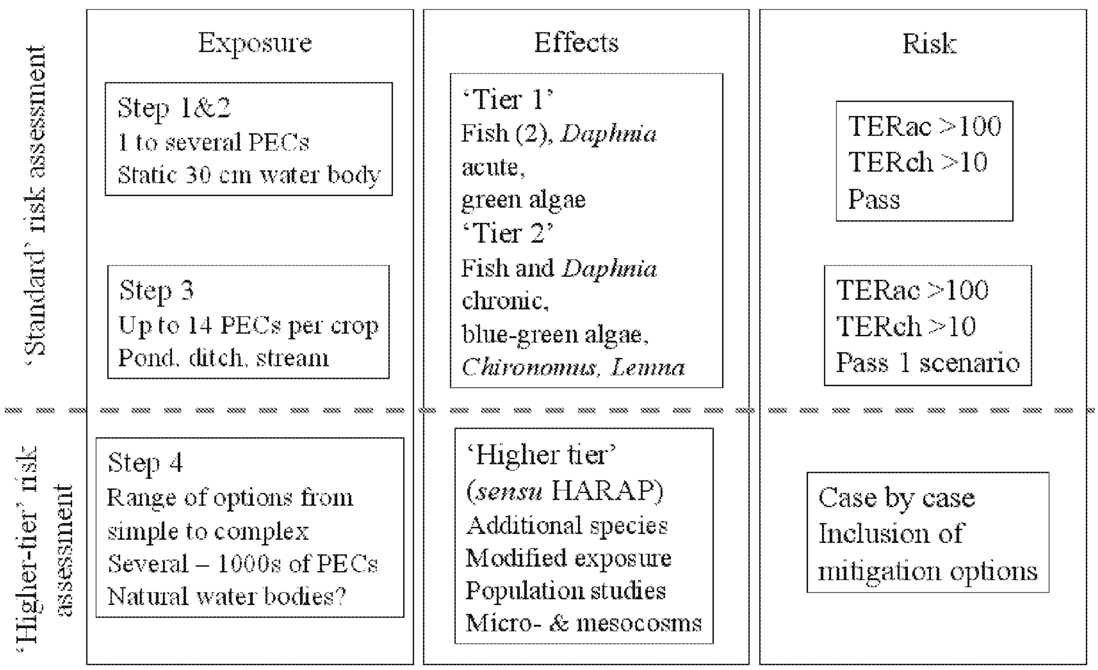
Directive 91/414/EEC requires that "risks of unacceptable effects for the environment are assessed" before any authorisation of a product is granted. It is further stated that "since the evaluation is based on a limited number of representative species, it shall be ensured that use of a plant protection product does not have any long term repercussions for the abundance and diversity of non-target species". In order to meet these environmental requirements, risk assessment is commonly based on "worst case" ecotoxicity and exposure assumptions and on the use of safety factors.

As with exposure assessment, the current approach to effects assessment under 91/414/EEC follows a tiered approach (SANCO 3268 rev. 3, 2002). At the lower tiers, acute and chronic laboratory toxicity tests with standard species (fish, invertebrates and aquatic plants) are conducted to determine the concentrations of the active substance and a representative formulated product that cause lethal and, where appropriate, sublethal effects. These are then compared to exposure concentrations from FOCUS Steps 1, 2 and 3 in an iterative process (Figure 3). In practice, results from lower-tier effects assessments could be compared to either Step 1-3 or Step 4 exposure calculations and similarly results from higher tier effects assessments could be compared to either Step 1-3 or Step 4 exposure calculations.

Whilst recognising that there are already well-defined options for conducting higher-tier ecotoxicity studies (SANCO, 2002), the FOCUS surface waters scenarios group recommended that at higher tiers, all of the options for effects and exposure refinement along with mitigation options should be considered in order to select the most appropriate path for further risk refinement at Step 4. Consequently, as part of the remit of the Work Group, a subgroup was established to discuss whether there were further possibilities for incorporating ecological considerations into Step 4 assessments.

Figure 3. Overview of the Aquatic Risk Assessment Process Subsequent to the Recommendations of the FOCUS surface water scenarios report and EU Aquatic Ecotoxicology Guidance Document (SANCO/3268/2001 rev. 4 (final)).

NB In practice, results from higher-tier effects assessments could be compared to Step 1-3 calculations, and similarly results from Step 4 exposure calculations could be compared to lower-tier effects assessments



During the course of its discussions, the Ecology Subgroup identified a number of key areas where ecological and ecotoxicological considerations could provide opportunities for refined risk assessment at Step 4. These were categorised into a number of topic areas, namely:

1. ***Definition of the ecological characteristics of the surface water scenarios***. The FOCUS Surface Water Scenarios identify three types of water bodies (ditches, streams and ponds) across the ten EU scenarios which cover a range of climates and soil types (in total fifteen different water bodies). Due to differences in local conditions (abiotic and biotic factors) and biogeographical considerations (the distribution of species), the ecological composition of these water bodies is likely to vary. These ecological differences could be used to differentiate the water bodies, for example by defining and grouping assemblages of organisms (e.g. according to their ecological traits) for each scenario/water-body combination. Such information could potentially be useful in further refining effects assessments, or in implementing suitable mitigation options. Furthermore, these local factors could influence toxicity either through interaction with the toxicant, or through the influence of multiple stressors or toxicants. Defining the ecological characteristics of the water bodies

could also help to refine exposure assessments by including biotic (e.g. macrophytes) and abiotic (e.g. pH) factors that may influence pesticide fate.

2. ***Relating the exposure profile at Step 3 to potential for effects***. Most lower-tier effects studies are conducted with maintained exposure concentrations. The Step 3 scenarios produce concentration profiles that can vary substantially with time. The group considered the potential options for including such varying exposure profiles in higher-tier risk assessments.

3. ***Factors influencing recovery***. Moving to the landscape level gives further options for considering recovery both from within the water body of concern ('internal recovery') and also from neighbouring water bodies ('external recovery') through considering dispersal mechanisms.

These points are elaborated below and, where possible, recommendations for future work have been made. SETAC (2005) summarises current knowledge on the effects of pesticides in the field.

6.2 Definition of the ecological characteristics of the surface water scenarios

6.2.1 Factors that influence community composition

At present under 91/414/EEC, risks to aquatic organisms are assessed using representative sensitive species from different trophic levels to determine the potential for effects from pesticide exposure. Uncertainty factors are then applied to account for potential differences in sensitivity between the standard test organisms and the range of species found in the environment (see Figure 3). This approach has generally been shown to be protective of effects observed in field (microcosm/mesocosm) studies (Brock et al., 2000 a &b). As the risk assessment is progressively refined, species additional to the standard organisms are also tested (either in laboratory or field studies). This reduces uncertainty associated with variability in inter-species sensitivity, and allows a re-evaluation of the uncertainty factor on a case-by-case basis (Campbell et al., 1998; EFSA, 2005b; 2006b).

One issue that has been discussed frequently in the development of higher-tier effects assessment is that at present there is no clear definition of the communities that are the intended protection target under 91/414 (see for example Giddings *et al.*, 2002). This means that it can be difficult to determine how applicable are data from single species testing or micro/mesocosm studies to the range of water bodies that occur across the EU. Nonetheless, reviews of mesocosm data from different latitudes and in different types of systems have generally indicated that effects thresholds are often similar, irrespective of the study location or system type (Giddings *et al.*, 2002). However, it seems likely that significant progress in the application of higher-tier data could be achieved if the assemblages of organisms that occur in different surface waters across the EU were better defined. Any consideration of protection targets needs to consider the ongoing discussions concerning the relationship between 91/414/EEC and the Water Framework Directive.

Understanding the relationship between environments and organisms is a basic aim of ecology. In the freshwater sciences, substantial research efforts have been conducted over the last three decades into the factors that determine species composition in surface waters (often as a result of the need to compare data from biological monitoring programmes with that which would be expected under reference conditions). One of the fundamental concepts that has emerged is that habitat type tends to determine the biological traits of organisms (and hence species) that live in them (the habitat templet or template theory of Southwood, 1977). A number of studies have demonstrated links between the species present and factors such as flow and substrate types (Statzner et al., 1997; Townsend et al., 1997). These have indicated that if the local habitat conditions are known, then the likely life-history attributes of organisms living there can be predicted, and with sufficient biogeographical information, likely species composition can be assigned to the water body.

A number of predictive models and tools have also been developed. Examples include *i.a.*, MOVE for aquatic vascular plants (cf. Bakkenes et al., 2002); RISTORI for aquatic macrofauna in the Netherlands (Durand and Peeters, 2000, Verdonschot et al., 2003); RIVPACS for macroinvertebrates in the UK (Wright et al., 2000); AQEM (www.aqem.com) for riverine macroinvertebrates; PSYM for ponds in the UK (http://www.brookes.ac.uk/pondaction/PSYM2.htm); small riverine fish (Mastrorillo et al., 1999); plants and macroinvertebrates in ditches, streams, ponds and rivers in agricultural areas (Biggs et al., 2007) and Illies' classification of European limnofauna (Illies, 1978).

Further work is also currently underway to develop such approaches under the EU Water Framework Directive (e.g. the StaR – Standardisation of River Classification Project www.eu-star.at). It is clear that for many aquatic organisms, data and models are available currently or will be in the near future. Broad organism assemblage scenarios could first be derived for the different types of water body (pond, ditch and stream) and then further development could generate assemblages for the fifteen surface water body / scenario combinations derived for the FOCUS surface water scenarios at Step 3. ***[Recommendation***

17] It is therefore recommended that in the future, ecological scenarios are further developed to accompany the fate scenarios at Step 3. The work would need to be accompanied by a consideration of use within regulatory practice and clear demonstration of the area and/or environmental conditions for which a particular scenario is representative.

Developing an ecological component to the surface water scenarios could be used in assessing and planning options to refine the risk assessment at higher tiers. Identification of the taxa typically associated with the scenarios allows any refinement to focus on those organisms that are likely to be of concern. This could assist in the interpretation of existing data (e.g. by examining the sensitivity of those taxa present or interpreting micro/mesocosm studies), and could also guide the development of new approaches such as ecological modelling (e.g. by using information on the life-history of such organisms to both refine the effects assessment and to make some forecasts of likely recovery rates from any effects – see below).

More details concerning the factors that influence the composition of aquatic communities in the landscape can be found in Volume 2 (Section 3.2). Of the many variables that influence the diversity of aquatic ecosystems, perhaps the key factors are biogeographical location, flow regime, and substrate type. With this sort of information, even if empirical methods are not available, it is usually possible for the expert limnologist to predict the taxa that will be present. Based on the properties of the fifteen water body / scenario combinations in the surface water scenarios, it therefore seems likely that it would be possible to begin to define ecological assemblages. The level of detail that would be achievable would vary among taxonomic groups and types of water body. For example, for macroinvertebrates and macrophytes, there are probably sufficient data for small streams and ditches to generate such ecological scenarios, but data are somewhat more limited for ponds. A preliminary summary table of likely data availability and feasibility of collecting data for the different water body types and certain taxonomic groups is shown in Table 11.

Table 11: Indication of data availability and feasibility of collection for different taxonomic groups in different water bodies – these are very broad generalisations. Information tends to be very patchily distributed.

Taxonomic group	Pond		Ditch		Stream	
	Availability	Feasibility	Availability	Feasibility	Availability	Feasibility
Fish	Poor/moderate	Low	Moderate	Moderate	High	High
Macroinvertebrates	Moderate	High	Moderate	High	High	High
Zooplankton	Poor	High	Moderate	High	n.a.	n.a.
Macrophytes	Moderate	High	Moderate	High	Moderate	High
Phytoplankton	Poor	Moderate	Moderate	Moderate	n.a.	n.a.

n.a. = not applicable

It should be noted however that data availability tends to be patchy in the different Member States and water body types. In order to develop the ecological scenarios, it would be necessary to establish a group of expert limnologists from the various regions of Europe, and perhaps an extended network of European experts for consultation and checking (e.g. via a distributed network as proposed by the FreshwaterLife project www.freshwaterlife.org). It is envisaged that such a task would be comparable in scale and effort to the development of the FOCUS surface water Step 3 fate modelling scenarios (albeit without the need for modelling software development). Whilst recognizing that gathering detailed species-level information might be difficult, a useful initial step would be to define broadly the sorts of organisms that would be associated with the various water bodies at a low level of taxonomic resolution. This task could potentially overlap substantially with the activities being carried out under the Water Framework Directive to classify surface waters in the EU, and potential synergies with these efforts should be explored.

6.2.2 Ecology of temporary or ephemeral water bodies

Assessment of temporary or ephemeral water bodies was discussed by the Ecology subgroup. The fifteen water body / scenario combinations associated with the FOCUS surface water scenarios were established as permanent water bodies (to accommodate the current risk assessment paradigm under 91/414/EEC) with a minimum depth that is maintained by base flow and/or a weir. It was acknowledged that temporary or ephemeral water bodies are often important in agricultural areas: in the north of Europe, drainage ditches often dry out during summer months, and in much of southern Europe, all but the largest, unregulated surface waters are ephemeral, only filling during storm events or from seasonal rains. These sorts of water bodies contain communities that are quite different to those of permanent water as they are highly adapted to the changing conditions. They often include resilient species with relatively short life-cycles, high mobility and/or desiccation-resistant resting stages (so-called 'r strategists') that are able to exploit the high temporal variability in conditions. These types of organisms tend to be more resistant to a variety of disturbances (both physical and chemical) than organisms that are more closely associated with permanent waters (e.g. Townsend et al., 1997). ***[Recommendation 18] Further work is recommended to differentiate the ecology of ephemeral water bodies from that of permanent waters.*** This would provide further options for the development of risk mitigation measures based on the protection target. In the UK, such approaches have already been adopted. Under the LERAP (Local Environmental Risk Assessment of Pesticides) scheme, buffer zone requirements for dry ditches were differentiated from those for ditches holding water at the time of spraying – further information can be found at www.pesticides.gov.uk/farmers/leraps.htm.

6.2.3 Factors that affect toxicity – abiotic and biotic

An additional use of ecological scenarios would be to consider the potential influence of the biotic and abiotic properties of the water body on the expression of the toxicity of the pesticide. A detailed review has been conducted of abiotic factors such as pH, dissolved oxygen, and temperature that influence the response of aquatic organisms to chemical stressors (see Volume 2 Section 3.3.1). These factors may act either directly, e.g. on species' metabolism or reproduction rate, or indirectly because they may influence the bioavailability of chemicals to organisms. Generally, standard laboratory studies are performed under conditions where the bioavailability of the chemical is maximised as far as possible, and tests are performed on neonates and juveniles, which are typically more sensitive than later life stages. Consequently, the abiotic and biotic factors that prevail in the field may well ameliorate the effects of certain chemicals (for example, the co-occurrence of sensitive life stages and exposure to pesticide should be established). These factors can be included in higher-tier studies, particularly outdoor micro- or mesocosm studies. ***[Recommendation 19] For this reason, when establishing ecological scenarios, it is recommended that typical physical and chemical characteristics are included***.

Biotic factors such as density dependence (i.e., limitations of resource and competition) and predation can be an important influence on the effects resulting from pesticide exposure. A number of studies have reviewed these factors (see Volume 2 Section 3.3.3). At this time, the science is not well enough established to allow general recommendations to be made as to how such factors could be included in a systematic way. Biotic interactions are included in multispecies studies such as microcosms and mesocosms, but these studies are point estimates that cannot represent the spatial and temporal variation in biotic factors. Further research should examine these interactions.

6.2.4 Ecological factors that could influence exposure calculations

[Recommendation 20] It is recommended that when establishing ecological scenarios, due attention is given to defining those ecological factors that may also influence fate processes. The Step 3 scenarios deliberately excluded ecological factors such as macrophytes that may have a significant influence on the fate of the chemical and indicated that such factors could be considered at Step 4. Aquatic macrophytes often comprise a significant component of the biomass in aquatic ecosystems. Not only is this important from a structural perspective in relation to providing food sources and substrates for organisms, but macrophytes can have a substantial influence on the dissipation and degradation of pesticides (see for example Crum *et al.*, 1999; Hand *et al.*, 2001). Perhaps a future development should be to evaluate more routinely how aquatic plants influence the dissipation and degradation of pesticides in surface waters, and to include these factors in the exposure modelling (this can be done in TOXSWA already).

In addition, no account is taken currently of the influence of riparian vegetation on the exposure of surface waters. Riparian and aquatic vegetation can intercept spray drift and significantly reduce inputs (e.g. de Snoo, 2001). Such parameters could also be readily built into future refinements of the scenarios.

6.3 Relating the exposure profile at Step 3 to potential for effects

One key consideration in refining a lower-tier aquatic risk assessment is to evaluate how the maintained exposure in standard studies relates to the variable exposure predicted under field conditions. Although the standard tests are worst-case, and appropriate in that respect at the lower tiers, they do little to assist in our fundamental understanding of the toxicokinetics of a compound because they are expressed as the ambient concentration (EC/LC50s and NOECs are expressed as the concentration in the water or sediment phases), rather than the concentration in the organism that elicits the effect. Whilst in the past, modified exposure studies have been developed to explore these phenomena, these have generally been relatively simple studies that follow a simple dissipation curve, either through the addition of sediment to the test system or through the use of variable dosing systems (see DG SANCO, 2002, Campbell et al., 1998). In the future, such studies may be much more complex to perform due to the technical difficulties of simulating time-varying exposure profile at Step 3 in laboratory studies. Also, there may be several exposure profiles generated at Step 3 making the issue more difficult to tackle empirically. A review of this subject by Reinert et al. (2002) provides some useful discussion and recommendations.

Modelling approaches based on toxicokinetics and toxicodynamics have been developed and combine the dissipation characteristics of the compound with its uptake, distribution, metabolism and excretion (Section 3.3.3.4 of Volume 2). These models may allow the potential for effects to be estimated over a wide range of exposure conditions, including evaluating the potential impact of multiple exposure peaks. However, a wider evaluation of available models is required before use within regulatory procedures can be considered. ***[Recommendation 21] Further development of the basic science, experimental options and modelling in this area is recommended.***

6.4 Factors influencing recovery

Discussions concerning recovery were subdivided into two categories: recovery from within the water body of concern ('internal recovery') and recovery from neighbouring water bodies ('external recovery') considering dispersal mechanisms. Dispersal can be active (e.g. by flying or crawling) or passive (mediated by other organisms and water- or wind-borne transport of propagules). At present, only limited data on such processes are available in the literature. A detailed discussion of the two processes can be found in Volume 2, Section 3.5.2.

Over recent years, several models for predicting internal recovery rates have been developed, and both HARAP and CLASSIC identified these approaches as potentially useful for higher-tier risk assessment, although still requiring significant development work. Methods for quantifying population recovery rates have recently been discussed by Barnthouse (2004), and a SETAC Pellston workshop in 2003 extensively reviewed population-level approaches in ecological risk assessment, including discussion and examples of potential modelling approaches (publication in preparation). Further useful information and guidance can be found in these publications. Generally, the use of modelling approaches should be considered on a case-by-case basis, and is not particularly amenable to specific guidance at this stage.

One of the problems with population modelling is that often the life-history data that are required to parameterise the models are not readily available. One approach that has been suggested to overcome this is the use of models with simplified life-history scenarios (Calow *et al.*, 1997). Such an approach may constitute a useful first tier, especially for exploring those types of life history that may be vulnerable to a particular pesticide. Where reasonable amounts of life-history data are available, individual-based models can be developed for a specific organism to estimate recovery rates under a range of conditions. However, in the future in order to improve the potential for the use of population models, efforts should be made to collect life-history data. A number of projects are currently aiming to do this, including the FreshwaterLife project (www. Freshwaterlife.org) and the UK PSD WEBFRAM project. ***[Recommendation 22] It is recommended that research into these approaches is supported and continued in the future.***

External recovery has so far received much less attention than internal recovery, although it is acknowledged to be an important process. Relatively little work has been carried out into the development of meta-population models, although the theoretical constructs have been developed (Wiens, 1997). There are also relatively few data concerning the dispersal of aquatic organisms through the landscape, although research interest in this area is growing (e.g. Konrad et al., 1999; Bilton et al., 2001; Purse *et al.*, 2003). Such approaches may prove useful for landscape level assessments in the future, but further work is needed to develop practical tools. Any assessment would clearly need to demonstrate the presence of unimpacted systems able to act as sources for recolonisation.

6.5 Ecological effects of mixtures of pesticides.

An additional point of discussion arose during the course of the Working Group's meetings. There may be the potential for organisms to be exposed to a range of toxicants and this becomes particular pertinent when dealing with risk assessment at the catchment level. A review of the different models of mixture toxicity has been conducted (see Volume 2, Section 3.3.2). As a starting point, the concept of concentration addition is a conservative means of estimating mixture toxicity (except where synergy occurs). However, one of the problems facing the implementation of such approaches is the large number of permutations of mixture combinations and concentrations. This means that implementing such approaches into the pesticide registration procedure would not be easily achieved. A recent semi-field study in the Netherlands has investigated the effects on ditch mesocosms of the combinations of products typically used in a Dutch potato crop (Arts *et al.*, in prep). The results indicated that assessments of effects of individual compounds were predictive of the effects seen when a range of compounds were applied to the system, suggesting that the current risk assessment scheme based on individual substances is probably protective. Nevertheless, further research is needed to obtain a comprehensive review of field impact of multiple stressors. Results of this research can then be discussed within the context of the level of protection attained at the different levels of refinement of the risk assessment.

7 RECOMMENDATIONS FOR FURTHER WORK

Recommendations for implementation and further work for each of the subgroup discussions are included in the summary (Volume 1) and detailed technical (Volume 2) reports. In its consideration of the state of development and potential future use of the landscape and mitigation approaches at Step 4, the Working Group made the following over-arching recommendations for prioritising future work:

[Recommendation 23] A new working group should be considered to further improve landscape analysis, modelling and mitigation approaches. There is a need to harmonise methods for producing spray drift data and to develop harmonised spray drift models, and an urgent need for more work on drainage and runoff. There is also a need to formalise the generation of landscape factors for consistency, as well as the appropriate scale to use for these analyses. This group could also contribute to the upgrading of the existing FOCUS surface water tools to facilitate Step 4 calculations. Key research needs to support the activities of this group would be:

- Research into mitigating exposure via drainflow (particularly restrictions based on soil vulnerability) and surface runoff (influence of conservation tillage, lateral transfer beneath vegetated buffers, modelling);
- Consideration of process-based modelling of spray drift (including the influence of formulation and crop structure);
- Consideration of mitigation for atmospheric deposition, reflecting any recommendations on this topic from the FOCUS air group;
- Generic research to support dissemination of mitigation approaches and uptake by end users;
- Additional general and model-specific research recommendations for further developing surface water exposure models were made in the FOCUS surface water report (FOCUS 2002);
- The proactive development of a set of landscape-level information related to specific crop/climate/exposure regimes. This may include a set of landscape-level data for use in refinement of Step 3 scenarios, as well as additional data suitable for the implementation of catchment level modelling, or to provide input distributions

for probabilistic modelling approaches. The emphasis would again be on improving risk assessment at the edge-of-field, although possibilities for assessment at the catchment scale should be further explored.

[Recommendation 24] A new working group should be considered to develop the ecological characteristics of the FOCUS surface water scenarios for use in higher-tier exposure modelling and effects assessments. It is anticipated that such a group would need to be similar to the FOCUS surface water scenarios group in terms of size and scope. Key research needs to support the activities of this group would be:

- The development of a process for collecting, compiling and categorising ecological data for surface waters (there is clear overlap here with activities under the Water Framework Directive). This could start with a detailed review of the available literature;

- Further work to clarify the influence of interactions of ecological factors and observed effects (e.g. the role of density dependence, overlap between ecoregions/habitats, predator-prey interactions, environmental stressors). Further detailed review of the literature should be performed;

- Research into the influence of dispersal and recovery. Metapopulation models would need to be developed to support this, and there would be a need to collate available life-history data;

- Further work to develop toxicokinetic models for use alongside FOCUS exposure profiles.

[Recommendation 25] Whilst the work presented here has focused on aquatic systems, many of the methods and approaches may be transferable to the terrestrial compartment. Nevertheless, complementary approaches should be developed for terrestrial systems in the future. Lower-tier terrestrial exposure assessment has not been addressed via FOCUS and it would be essential to build on existing guidance and methods developed under other initiatives.

8 REFERENCES

Arts G.H.P, Belgers J.D.M., van Rhenen-Kersten C.H., van Wijngaarden R.P.A., Roessink I., Maund S.J. & Brock T.C.M. (in prep.) Ecological impact of drift emission of pesticides from potato fields in experimental ditches.

Bakkenes M., De Zwart D., Alkemade, J.R.M., 2002. MOVE national Model for vegetation version 3.2. RIVM report 408657006/2002.

Barnthouse LB. 2004. Quantifying population recovery rates for ecological risk assessment. Environmental Toxicology and Chemistry, 23, 500–508.

Biggs J, Williams P, Whitfield M, Nicolet P, Brown CD, Hollis JM, Maund SJ, Arnold DJ, Pepper T (2007). The freshwater biota of British agricultural landscapes. *Agriculture Ecosystems and Environment* 122:137-148.

Bilton D.T., Freeland J.R. and Okamura B., 2001. Dispersal in freshwater invertebrates. Annual Reviews Ecology Systematics, 32, 159-181.

Brock T.C.M., Lahr J. and Van den Brink P.J., 2000 a. Ecological risks of pesticides in freshwater ecosystems. Part 1: Herbicides. Alterra report 088, 127 pp.

Brock T.C.M., Van Wijngaarden R.P.A. and Van Geest G.J., 2000 b. Ecological risks of pesticides in freshwater ecosystems. Part 2: Insecticides. Alterra report 089, 142 pp.

Calow P, Sibly RM, Forbes V. 1997. Risk assessment on the basis of simplified life-history scenarios. Environmental Toxicology and Chemistry, 16, 1983-1989.

Campbell P.J., Arnold D.J.S., Brock T.C.M., Grandy N.J., Heger W., Heimbach F., Maund S.J. and Streloke M., 1999. Guidance document on Higher Tier Aquatic Risk Assesment for Pesticides (HARAP), SETAC Europe Publications, Bruxelles.

Conrad, K.F., Willson, K.H., Harvey, I.F., Thomas, C.J. & Sherratt, T.N. (1999) Dispersal characteristics of seven odonate species in an agricultural landscape. *Ecography*, **22**, 524-531.

Crum SJH, van Kammen-Polman AMM, Leistra M. 1999. Sorption of nine pesticides to three aquatic macrophytes. Archives of Environmental Contamination and Toxicology, 37, 310-316.

De Snoo GR. 2001. Drift reduction by vegetation and application technique. In: Work-shop on Risk Assessment and Risk Mitigation Measures in the Context of the Authorisation of Plant Protection Products (WORMM) 27-29 September 1999. Eds R Forster & M Streloke, Mitt. Aus der BBA, Heft 383, Berlin, pp 94-98.

DG SANCO. 2002. Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC. Sanco/3268/2001 rev.4 (final) 17 October 2002.

Dubus, I.G., Brown, C.D., Beulke, S., Turner, N.L. (2002). Uncertainty and probabilistic approaches to pesticide fate modelling. Cranfield University report for DEFRA project PL0548, Silsoe, Bedford UK, p138.

Dubus, I.G., Brown, C.D., Beulke, S. (2003). Sensitivity analyses for four pesticide leaching models. *Pest Management Science* 59:962-982.

Durand, A.M., E.T.H.M. Peeters, 2000. Effects of interventions in water management on aquatic communities. Species approach, phase 2: predictive value and usefulness. Witteveen en Bos.

ECOFRAM (1999). www.epa.gov/oppefed1/ecorisk.

EFSA (2005a). Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from Commission related to the evaluation of dimoxystrobin in the context of Council Directive 91/414/EEC. 16 February 2005.

EFSA (2005b). Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the assessment of the acute and chronic risk to aquatic organisms with regard to the possibility of lowering the uncertainty factor if additional species were tested. 14 December 2005.

EFSA (2006). Opinion of the Scientific Panel on Plant Protection products and their Residues on a request from EFSA on the Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. 13 December 2006.

EFSA (2006a). Opinion of the Scientific Panel on Plant Protection products and their Residues on a request from the Commission on the safety of aldicarb MRLs. 19 October 2006.

EFSA (2006b). Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from the EFSA related to the aquatic risk assessment for cyprodinil and the use of a mesocosm study in particular. 01 March 2006.

FOCUS, 2002. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Docu-ment Reference SANCO/4802/2001-rev.2. 245 pp.

Giddings J.M., Brock T.C.M., Heger W., Heimbach F., Maund S.J., Norman S.M., Ratte H.T., Schäffers C., and Streloke M., 2002. Community-Level Aquatic System Studies-Interpretation Criteria (CLASSIC). Pensacola, FL, USA, SETAC Publications.

Hand LH, Kuet SF, Lane MCG, Maund SJ & Hill IR. 2001. Influences of aquatic plants on the fate of the pyrethroid insecticide lambda-cyhalothrin in aquatic environments. Environmental Toxicology and Chemistry, 20, 1740-1745.

Hart, A (2001). Probabilistic Risk Assessment for Pesticides in Europe: Implementation & Research Needs, Report from a workshop in The Netherlands, Central Science Laboratory, Sand Hutton, York, UK.

Illies, J., 1978 Limnofauna Europaea. Gustav Fischer Verlag, Stuttgart

Kreuger J, Peterson M, Lundgren E (1999). Agricultural inputs of pesticide residues to stream and pond sediments in a small catchment in southern Sweden. Bulletin of Environmental Contamination and Toxicology 62:55-62.

Mastrorillo S, Lek S, Dauba F, Belaud A. 1997. The use of artificial neural networks to predict the presence of small-bodied fish in a river. Freshwater Biology, 38, 237-246.

Purse BV, Hopkins GW, Day KJ, Thompson DJ. 2003. Dispersal characteristics and management of a rare damselfly. Journal of Applied Ecology, 40 (4), 716-728.

Reichenberger S, Bach M, Skitschak A, Frede,H-G. 2007. Mitigation strategies to reduce pesticide inputs into ground- and surface water and their effectiveness; a review. Science of the Total Environment (in press).

Reinert KH, Giddings JM, Judd L 2002. Effects analysis of time-varying or repeated exposures in aquatic ecological risk assessment of agrochemicals. Environmental Toxicology and Chemistry, 21 (9), 1977-1992.

SETAC (2005). EU & SETAC Europe Workshop (2003), Le Croisic, France. Effects of pesticides in the field. Editors: Liess M, Brown C, Dohmen P, Duquesne S, Hart A, Heimbach F, Kreuger J, Lagadic L, Maund S, Reinert W, Streloke M, Tarazona JV. Society of Environmental Toxicology and Chemistry, Brussels.

Southwood TRE. 1977. Habitat, the templet for ecological strategies? Journal of Animal Ecology, 46, 337-365.

Statzner B, Hoppenhaus K, Arens M-F, Richoux P. 1997. Reproductive traits, habitat use and templet theory: a synthesis of world-wide data on aquatic insects. Freshwater Biology, 38, 109-135.

Styczen, M., Petersen, S. Sørensen, P.B., Thomsen, M and Patrik, F. (2004): Scenarios and model describing fate and transport of pesticides in surface water for Danish conditions. - Ministry of Environment, Danish Environmental Protection Agency, Pesticides Research No. 63.

Townsend CR, Doledec S, Scarsbrook MR. 1997. Species traits in relation to temporal and spatial heterogeneity in streams: a test of habitat templet theory. Freshwater Biology, 37, 367-387.

US EPA (1997). Guiding principles for Monte Carlo analysis. US Environmental Protection Agency, Risk Assessment Forum, Washington DC (available at www.epa.gov).

Wauchope RD (1978). The pesticide content of surface water draining from agricultural fields – a review. Journal of Environmental Quality 7:459-472.

Wiens, J.A. (1997) Metapopulation dynamics and landscape ecology. Metapopulation Biology: Ecology, Genetics and Evolution (eds I. Hanski & M.E. Gilpin), pp. 43-62. Academic Press, San Diego, CA.

Winkler, R. (2001): Concept for an assessment of the entry of plant protection products in surface water and groundwater, with special consideration of surface run-off (Documentation of the EXPOSIT model) [in German]. Umweltbundesamt - Einvernehmensstelle Pflanzenschutzgesetz.

Wright JF, Sutcliffe DW, Furse MT. 2000. Assessing the biological quality of fresh waters: RIVPACS and other techniques. Freshwater Biological Association, 400pp.

A1 ILLUSTRATION OF A POSSIBLE APPROACH TO IDENTIFICATION OF NEW SCENARIO LOCATIONS AT STEP 4

The example below describes one possible approach to identifying a new scenario location at step 4. It is intended to be illustrative and is not intended to be prescriptive. A detailed opinion of the illustration is available from PPR (2006), and this also includes suggestions for an alternative approach that should be considered before embarking on development of a new scenario location.

The aim of the FOCUS Surface Water Scenarios work group was to develop a limited number of "realistic worst-case" surface water scenarios for Step 3 simulations, that were broadly representative of agriculture in major agricultural production areas of the EU. For that purpose six drainage and four runoff scenarios, i.e. combinations of soil and climate properties, were identified that integrate a realistic combination of worst-case characteristics for runoff and drainage losses. After selection of scenario areas, representative field sites were selected, which should exhibit the defined scenario characteristics. In most cases the field sites were chosen because extensive monitoring data were available to facilitate model parameterisation and possible future validation studies, however some scenarios (e.g. D5 and D6) represent educated guesses based on expert judgement without previous calibration against experimental data.

In order to limit the number of simulation runs in Step 3 to a manageable size, the defined surface water scenarios are used to simulate pesticide applications to 23 crops, which were assigned to each site according to the probability of occurrence in the respective agricultural region.

In summary the FOCUS surface water scenarios represent standard scenarios that can be used for the purpose of EU Annex I listing since they reflect realistic and vulnerable use conditions. Nevertheless a potential issue is likely to arise for more precise surface water assessments at Step 4: Do the scenarios represent a realistic range of PECsw for a specific compound within its typical area of use?

If in the course of a risk assessment it becomes obvious that a particular use is not well represented by any of the FOCUS surface water scenarios, it might be appropriate to identify those environmental settings in which the risk for surface water exposure associated with this use pattern is highest. The goal is to supplement the basic set of FOCUS scenarios to provide a range of PECsw for a particular compound at Step 4. In order to ensure consistency with Steps 1-3 it is recommended to follow a procedure that is close to the methods applied to identify the locations of the original Step 3 scenarios. The following section gives an example of how vulnerable environmental settings can be identified for crops that are currently not well represented in FOCUS surface water scenarios. Note that it was only attempted to provide a general guidance about the identification of new scenario areas in Step 4 by means of GIS methods. In this chapter it was not intended to provide recommendations about alternative modelling approaches that differ from the philosophy of FOCUS Step 3 scenarios and that might be relevant in the assessment of some speciality crops (e.g. fundamental changes of cropping parameters, size and characteristics of upstream area etc.). Furthermore, new crop-specific scenarios should not substitute existing surface water scenarios in Step 3 runs but could be used to refine the assessment at Step 4.

To illustrate the recommended procedure for identifying candidate regions for a refined surface water assessment, an imaginary use in olives has been chosen. It is therefore assumed that an aquatic risk assessment is undertaken for compound X, which is proposed for use on olives with Spain and Italy as the most important markets.

A1.1 Existing FOCUS step 3 scenarios

Two locations were identified by the FOCUSsw Group as appropriate for assessment of olives at Step 3. A location in southern France (R4) is therefore used for runoff simulations. A location in Greece (D6) is used to simulate drainage losses in Step 3. Both sites exhibit agronomic conditions that are realistic for olive growing, although neither scenario is located in primary olive cropping areas as shown by Figure A1.1 and A1.2.

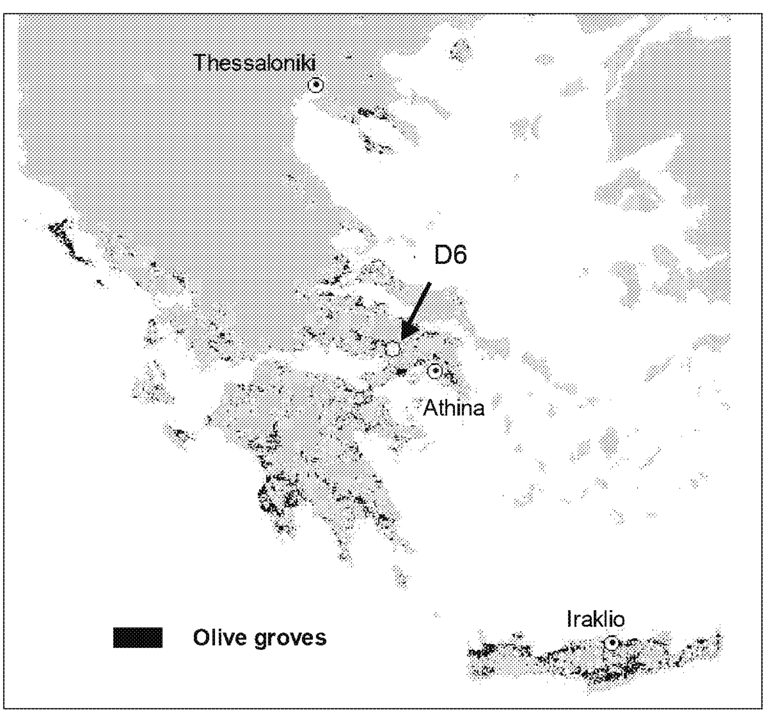


Figure A1.1. Olive groves in Greece and location of FOCUS weather station D6

[Source: Corine Land Cover, 1998]

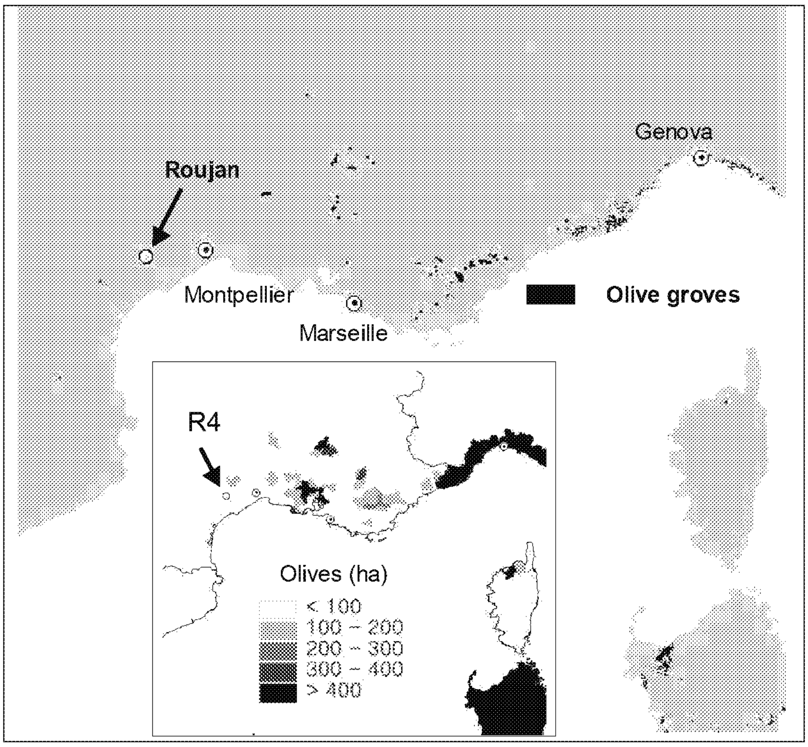


Figure A1.2. Olive groves in France and Northern Italy and location of the FOCUS weather station R4.

[Source: Corine Land Cover, 1998, SCEES, 2000, ISTAT, 1998]

In general the probability of occurrence of a certain crop at a location can be assessed by means of two datasets. Some perennial crops like olives or vineyards are included as separate classes in Corine Land Cover (Corine, 1998) and thus their regional importance can be visualised with a high spatial accuracy. In regions where these crops are grown only in small quantities it might be more appropriate to use agricultural census data to assess the regional importance of the target crop. The latter approach is also required to visualise fruit trees and field crops since Corine Land Cover does not differentiate between most crops.

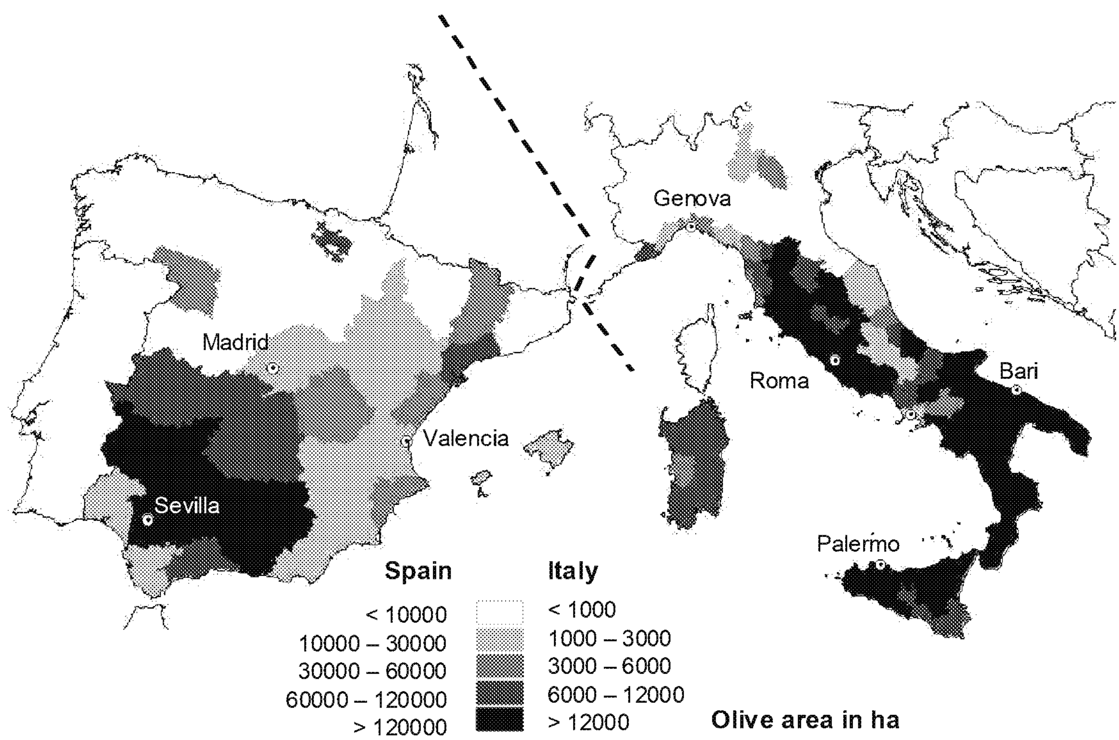
In the present example it can be concluded on the basis of agricultural census data and/or Corine Land Cover that olives are likely to be grown in the area covered by the scenarios R4 and D6. At Step 4, it becomes relevant to consider the range of conditions under which olives are grown. A Step 4 evaluation could focus on the problem: What is the realistic range of PECsw in the olive cropping area for which the compound is intended to be registered?

It is acknowledged that a number of approaches exist to derive realistic worst-case scenarios for exposure simulations. For the purpose of a Step 4 evaluation in the framework of FOCUSsw it is however recommended to ensure a consistent approach in all Steps. As a consequence. the methodology for deriving additional surface water scenarios should be as close as possible to the method applied by the FOCUS group to derive Step 3 scenarios.

A1.2 Identification of the potential scenario area for Step 4 simulations

For pragmatic reasons it is recommended to use the cropping area of a target crop as a first indicator to determine the area of interest. Figure A1.3 shows the olive area as indicated by agricultural census data. Note, that Spanish *provincias* are larger than Italian *provinzias*, and it is thus appropriate to consider a different threshold for relevance of a cropping area. In this example, a Spanish *provincia* with more than 10,000 ha olives was regarded as a relevant production area. In the case of Italy, a *provinzia* with more than 1000 ha was taken as a relevant production area. Another option is to normalise the data on the basis of total area or total cropped area.

Figure A1.3. Olive area (ha) in Spain and Italy.



A1.3 Consideration of climate properties

Recommended data source: MARS meteorological database. Interpolated weather data from 1975 – 2003 (depending on stations) in 50 x 50 km grid-cells. JRC Ispra. EU-Commission. [The following example analysis was performed with a similar dataset for illustrative purposes only since the MARS database was not available at the time. All climate parameters mentioned in the text are also available in MARS]

The initial selection of Step 3 FOCUSsw scenarios was pragmatically based on climate properties as the principal landscape factor. For that reason it is recommended that a Step 4 modelling study starts with an analysis of climate properties in a similar manner as was performed to identify FOCUSsw scenarios.

Table A1.1. Climatic classes to differentiate agricultural drainage and runoff scenarios (FOCUS 2002)

Average autumn and spring temperature [°C]	Class	Average annual recharge [mm]	Class	Average annual rainfall [mm]	Class
< 6.6	Extreme worst case	> 300	Extreme worst case	> 1000	Extreme worst case
6.6 – 10	Worst case	200 – 300	Worst case	800 – 1000	Worst case
10 – 12.5	Intermediate case	100 – 200	Intermediate case	600 – 800	Intermediate case
> 12.5	Best case	< 100	Best case	< 600	Best case

A1.3.1 Climate vulnerability for drainage scenarios at Step 4

Average autumn and spring temperatures as well as average annual rainfall volumes are readily available through MARS. For a simplified assessment of relative climate vulnerability it is nevertheless proposed to use annual average temperature, primarily because the relative climate vulnerability is similar when using annual average or seasonal temperatures (see Figure A1.4 to Figure A1.6). Nonetheless, a different approach might be appropriate in cases where the area of interest extends over various climate zones that differ significantly in terms of seasonal climate regime.

Average annual recharge was calculated by FOCUSsw on the basis of estimated evapotranspiration and annual rainfall since measured values for potential evapotranspiration are usually not available for large regions. A detailed description of the estimation procedure for evapotranspiration according to Penman is given in the MARS manual (MARS, 1997). It is important to note, however, that this method is exclusively based on climate properties and was not developed to account for soil and crop characteristics.

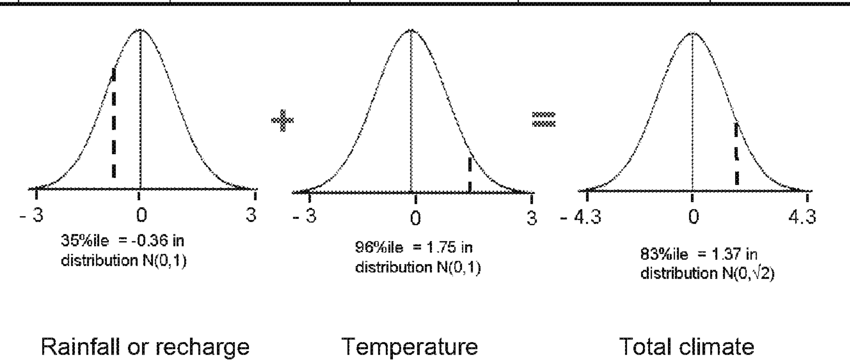
For pragmatic reasons, winter rainfall is probably the most appropriate parameter for the characterisation of relative vulnerability for drainage losses. The rationale for using winter rainfall is based on the hypothesis that field drains are primarily active between October and March when soils are saturated and water demand of crops is low. The rainfall sum between October and March is also more readily available on a regional level.

To assess the degree of vulnerability for a grid cell it is crucial to know its relative ranking compared to climate conditions in the entire growing area of a crop. Temperature as well as precipitation amounts in each grid cell can therefore be expressed as the x^{th}-percentile value of rainfall or mean temperatures. It is important to note that only in very rare cases does the 90^{th} percentile of worst-case precipitation coincide with 90^{th} percentile worst-case temperatures. The joint percentile value of temperature and rainfall should be calculated in order to assess adequately the climate characteristics at the scenario location.

Assuming that both variables are normally distributed and have a similar effect on leaching losses it is possible to add two normal distributions with a mean of zero and standard deviation of 1. The individual percentile values for e.g. rainfall and temperature give rise to a corresponding percentile value in the normal distribution. The joint distribution percentile is the value (p_rainfall + p_temperature) in the joint normal distribution with a standard deviation of $\sqrt{2}$. Table A1.2 illustrates the approach by means of a numerical example.

Table A1.2. Example for the calculation of joint percentiles for rainfall/ recharge and temperature.

Single probabilities				Joint probability	
1 Single percentile	2 Single percentile	3 Corresponding values in the Normal cumulative distribution function with mean of 0 and **stdev of 1**	4	5 col 3 + 4	6 Percentile of col. 5 in the joint Normal distribution with mean of 0 and **stdev of $\sqrt{2}$**
Rainfall or Recharge 0.35	Temperature 0.96	Rainfall or Recharge -0.385	Temperature 1.750	1.365	**0.83**



It is important to note that the overall goal of spatial vulnerability assessments is the relative ranking of risk instead of a classification of risk in terms of absolute values. This means that the risk of pesticide losses should not be classified according to classes of rainfall volumes and temperature classes but in terms of percentiles of 'worst-casedness'. The specific contribution of rainfall/recharge or temperature to the overall climate vulnerability is probably also dependent upon compound properties, in particular upon the degradation rate in soil. In this way, the proposed approach represents a pragmatic solution by treating rainfall and temperature as equally important factors. An extensive sensitivity analysis would be required on a regional scale and for a range of compound properties to determine the exact contribution of rainfall and temperature. Another important simplification is the assumption of a normal distribution of rainfall. Depending on the size of the area of interest the distribution of rainfall volumes is often not normally distributed.

Spatial analysis of climate vulnerabilities: Temperature

The following maps illustrate the percentile approach. A first visual evaluation shows that a classification of temperature classes would result in similar regional clusters when using seasonal or annual average temperatures (see A1.4 to A1.6). Again it is emphasised that the selection of annual average temperatures or seasonal temperatures depends to a large extent on application periods and compound properties. Spring temperatures should be preferred over annual average temperatures for the environmental assessment of spring-applied chemicals with a short half-life (this suggestion applies in the definition of specific scenarios for use at Step 4; the more generalised approach based on annual average temperatures has been correctly used in defining the FOCUS SWS at Step 3).

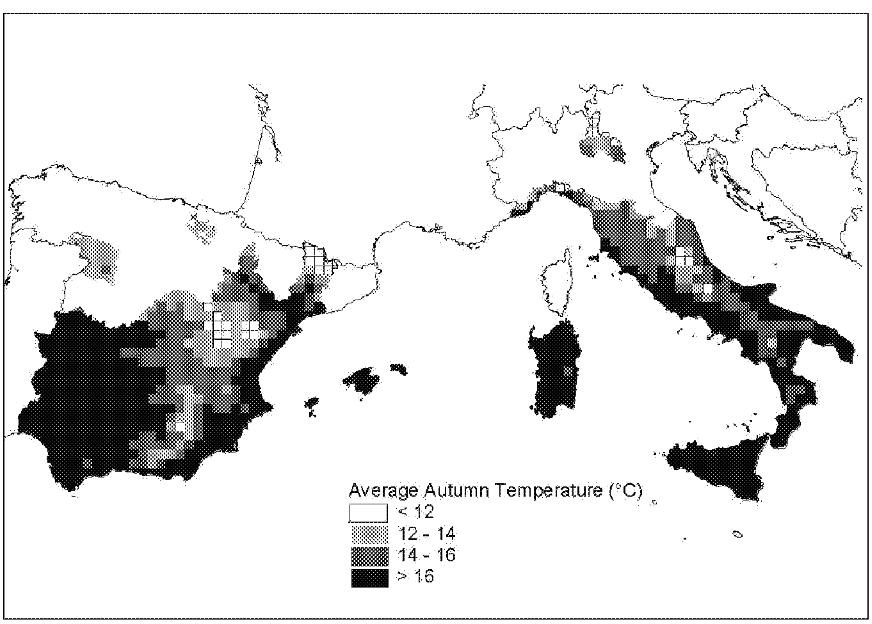


Figure A1.4. Average autumn temperature

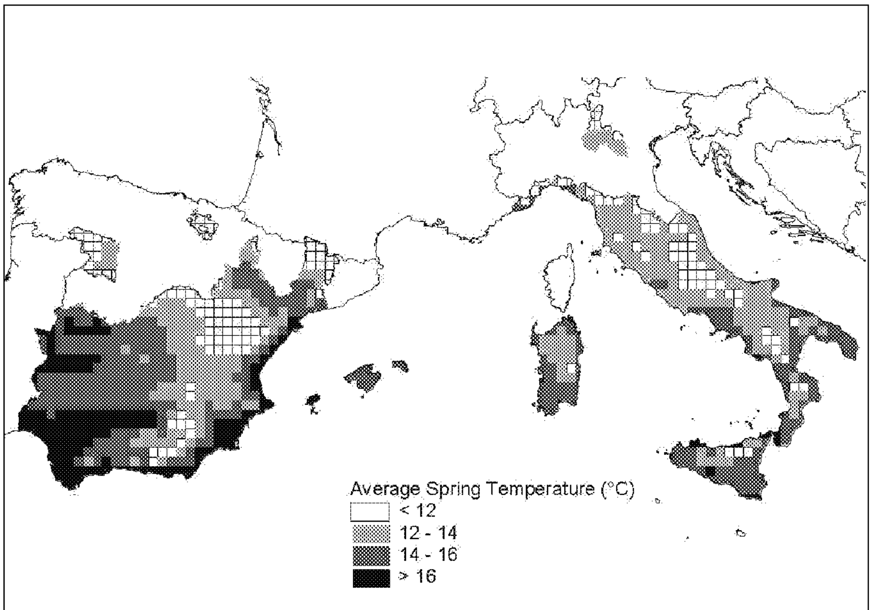


Figure A1.5. Average spring temperature

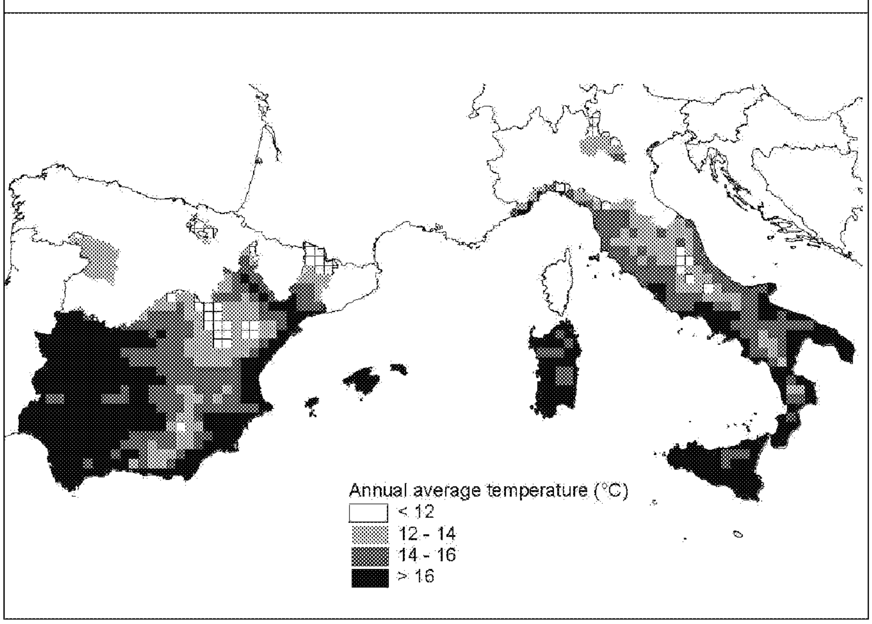


Figure A1.6. Annual average temperature

<u>Evaluation of climate vulnerabilities: Recharge and rainfall</u>

Figure A1.7 shows calculated recharge volumes for the potential olive area. Large areas show no groundwater recharge because of the very high evapotranspiration losses during summer. As a consequence, areas with higher recharge volumes are almost identical to areas with high winter rainfall volumes (see Figure A1.8).

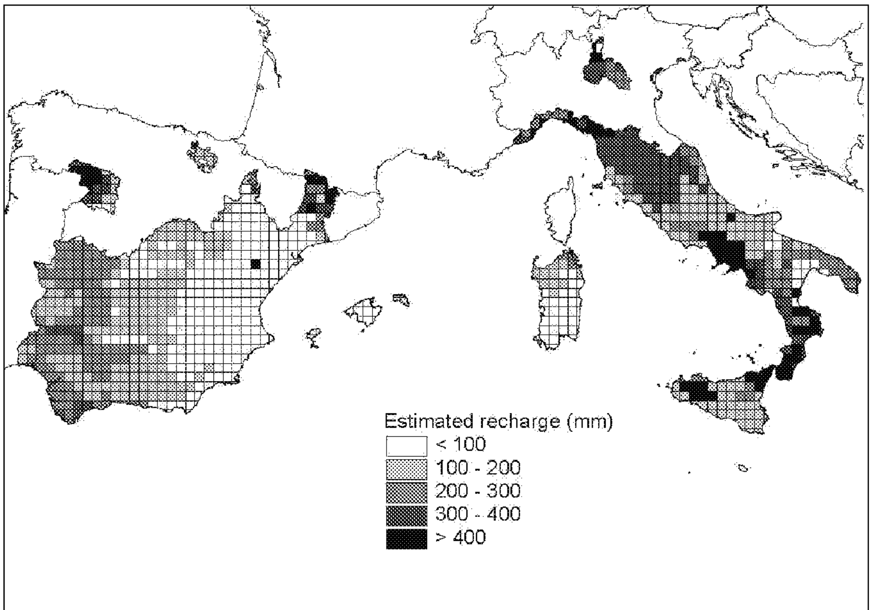


Figure A1.7. Annual average recharge

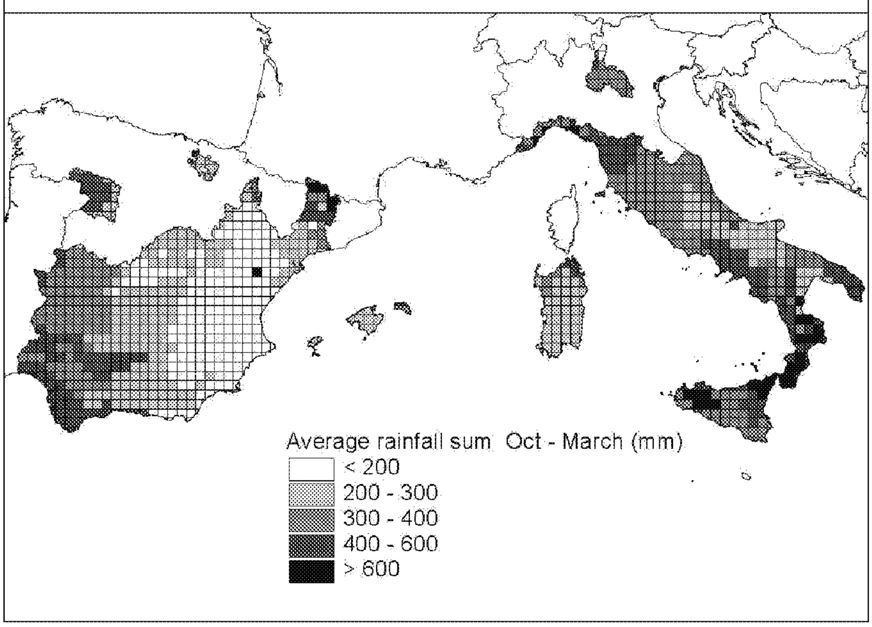


Figure A1.8. Annual average rainfall between October and March

The resulting climate vulnerability for drainage losses was calculated both for temperature and winter rainfall and for temperature and annual average recharge (Figure A1.9 and Figure A1.10). The calculated climate vulnerability is roughly similar for upper percentile ranges. Nevertheless slight differences were calculated for the medium percentile range. All weather grid cells that are located in altitudes > 600 m were excluded from the assessment to add more realism in the assessment. In this way it is avoided that climate stations in mountainous areas introduce a potential bias into the assessment. <u>It is important to note that the MARS climate databases contains only weather data that were recorded from weather stations in agricultural areas</u>. However, it is appropriate to exclude mountainous areas as temperatures were interpolated between weather stations on the basis of altitude.

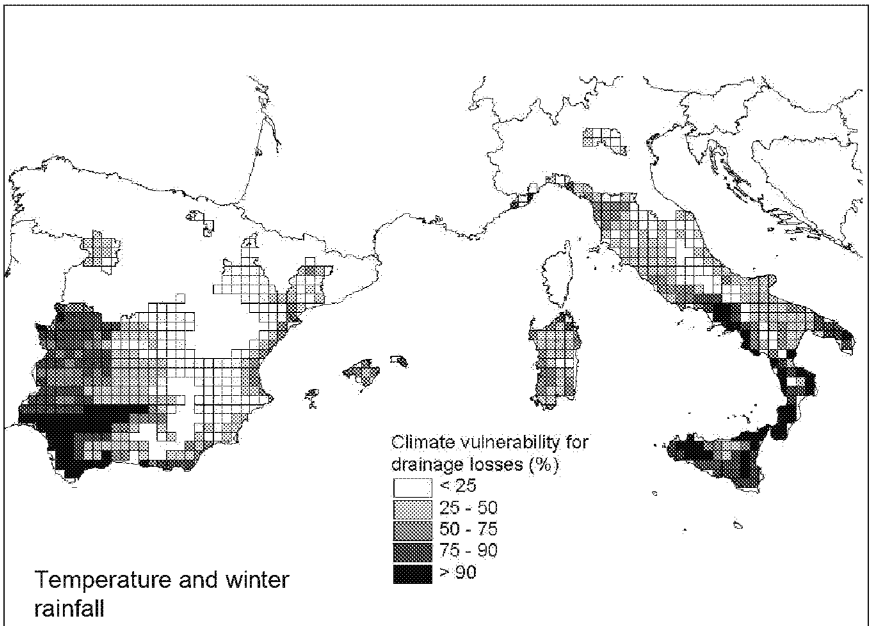


Figure A1.9. Climate vulnerability for temperature and winter rainfall for weather grid cells < 600 m altitude

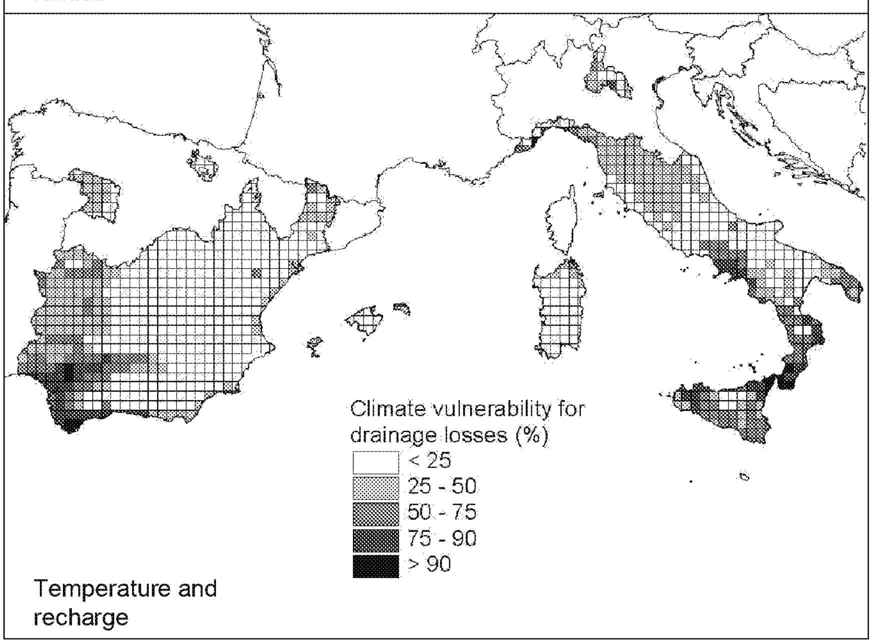


Figure A1.10. Climate vulnerability for temperature and average annual recharge

<u>Conclusions for the evaluation of climate vulnerability for drainage losses</u>

The result of the spatial analysis of climate vulnerability depends on the climatic parameters that are used in the spatial analysis. The results of an example analysis for olive areas showed that several parameters, e.g. seasonal temperatures vs. annual temperatures, gave approximately the same ranking of climate vulnerability for drainage losses. Nevertheless this conclusion might not hold true in all cases. As a general recommendation it is therefore proposed to decide on the basis of compound properties and the specific use conditions.

Annual average recharge and average winter rainfall can be used alternatively in most cases. The estimation of recharge based on climate parameters is however a first approximation only and includes several empirical assumptions that are subject to uncertainty.

Table A1.3. Considerations for the selection of climate parameters for the scenario identification process for drainage simulations.

Compound	Use	Recommended climate parameters	
Long half-life	Spring application	Annual average temperature	Annual average recharge or winter rainfall
Long half-life	Autumn application	Autumn temperature	Annual average recharge or winter rainfall
Short half-life	Spring application	Spring temperature	Annual average recharge or winter rainfall
Short half-life	Autumn application	Autumn temperature	Annual average recharge or winter rainfall

Note that the relevance of pesticide losses via drainflow should also be considered when performing a Step 4 assessment for a specific area.

A1.3.2 Climate vulnerability for runoff scenarios at Step 4

In principle, the calculation of climate vulnerability maps for runoff is similar to drainage losses. FOCUSsw used annual average rainfall volumes as the primary indicator, but runoff vulnerabilities can also be ranked using alternative indicators. The total pesticide loss with runoff depends largely on the amount of pesticide that is available at the soil surface at the beginning of a runoff event. Since active ingredients are subject to degradation, it is important to know how often runoff-producing rainstorms occur during the application season. In cases where the re-occurrence period of runoff events is long, the loss of compounds with a short half-life will be lower.

A comparison of rainfall data from Stockholm and Sevilla illustrates the problem. Both cities show the same long-term average rainfall with 555 and 559 mm per year (Rudloff, 1981). In Sevilla 77 % of total rainfall occurs between October and March whereas in Stockholm rainfall is distributed homogeneously over the year with 44 % of precipitation recorded in winter (probably snow in most cases). For statistical reasons, the greater winter rainfall in Sevilla results in a higher re-occurrence probability of runoff producing events between October and March and thus a higher probability that runoff occurs after application of autumn applied compounds. This difference is not visible when regarding annual average rainfall volumes.

Some weather services (e.g. the German Weather Service) provide nation-wide distribution functions that can be used to calculate long-term average return periods of runoff-producing rainstorms. Such procedures should be considered when identifying new locations for runoff scenarios and the reader is referred to the literature for advice on the practical implementation in spatial databases (Gumbel, 1958, Weiss 1964, DVWK, 1984, Huber et al. 1998). The basic requirement for the calculation of rainfall re-occurrence probabilties is the availability of daily rainfall data. In this way it is possible to use MARS data for the derivation of rainfall distribution functions for 24 h-events since the database includes daily rainfall data.

Table A1.4. Considerations for the selection of climate parameters for the scenario identification process for runoff simulations.

Compound	Use	Recommended climate parameters	
Long or short half-life	Spring application	Spring temperature	Spring rainfall or rainfall re-occurrence interval in spring
Long or short half-life	Autumn application	Autumn temperature	Winter rainfall or rainfall re-occurrence interval in winter

A1.4 Identification and parameterisation of Step 4 soil scenarios

A1.4.1 Considerations for drainage scenarios at Step 4

Ideally the scenario identification process would be restricted to drained soils. The respective information is, however, rarely available on the landscape level. Furthermore, the derivation of a realistic occurrence probability of field drains depends not only on landscape factors but also on economic parameters and agricultural policy. For the purpose of a landscape risk assessment, it is therefore often required to assume conservatively that all soils with potential waterlogging problems are drained. The FOCUS Surface Water Scenarios work group provided a proposal about the parameters in the EU soil map that could be used to define potentially drained agricultural land in the EU. The most straightforward way to identify potentially drained land is to use the prevailing water management system. The information on the water management system is however not complete in some countries. In this case, it is appropriate to use the FAO soil classification as an indicator about the occurrence of waterlogging.

Table A1.5. Soil properties which can be used to identify potentially drained land

Water management #	Potentially drained soil types (FAO)	Parent material
WM2 = 1,3,4,5 or WM1 = 1 and WR 2,3,4	All soils affected by groundwater and periodic waterlogging (gleyic or stagnic properties.)	Any parent material that indicates the absence of slope e.g. alluvial deposits

#As proposed by FOCUS (2002)

Potentially drained soils can be ranked according to parameters that are available for all soil polygons in the EU soil map such as dominant soil texture and organic carbon content. For pragmatic reasons it is proposed to select at least one soil that is prone to preferential flow and another, coarse textured soil that shows chromatographic flow of soil water.

A1.4.2 Considerations for runoff scenarios at Step 4

Runoff from agricultural soils is generated when the soil water content exceeds the infiltration capacity. In the presence of slope, any excess water is lost via surface runoff. Runoff losses are therefore independent from slope as soon as the inclination of a field exceeds a certain threshold of 2 – 3 % slope. In contrast, the transport of soil particles (*i.e.* soil erosion) is a function of slope because the magnitude of particle detachment is determined by the kinetic energy of rainfall and slope.

Based on the above-mentioned rationale it seems appropriate to use soil properties as the primary indicator for runoff since models like PRZM use slope information only for the prediction of erosion losses. Burgoa and Wauchope (1995) conducted an extensive review of reported pesticide losses with surface runoff and concluded that only compounds with a Koc of > 2000 ml g^{-1} are likely to be lost primarily with soil particles, *i.e.* are lost by means of erosion processes. Less sorbing compounds are primarily lost with runoff water. As a consequence, it is only required to consider slope information when erosion losses of highly sorbing compounds are simulated.

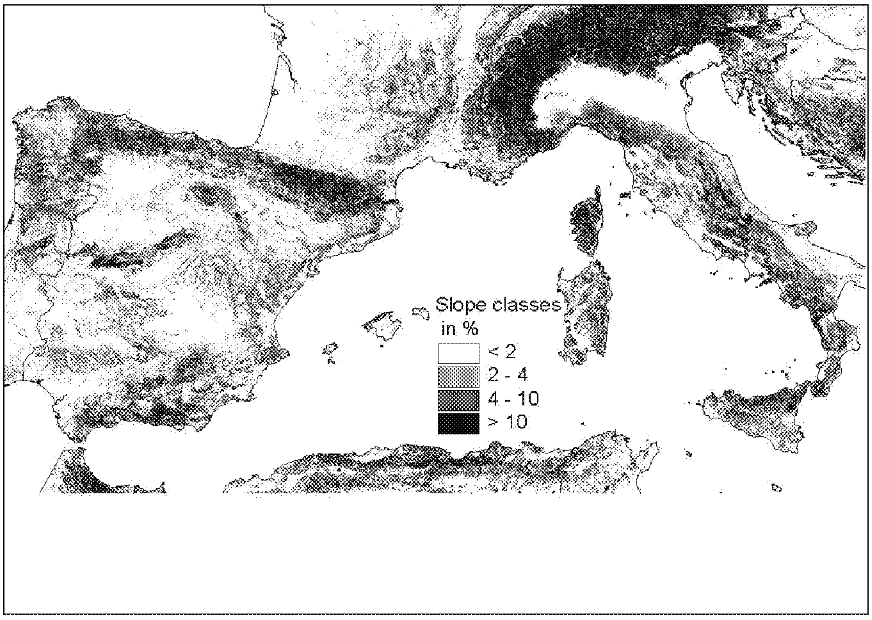


Figure A1.11. Slope classes as calculated on the basis of a digital elevation map (source: GTOPO30, USGS)

GTOPO30 = 30 arc seconds which is approximately 1 km
http://edcdaac.usgs.gov/gtopo30/gtopo30.html
Higher resoluted digital elevation maps (down to 90m grid size) are available on a global scale in the near future

The runoff susceptibility of agricultural soils is usually described by means of the empirical curve number approach which was originally developed for flood predictions in the US. This method classifies soils according to land use and infiltration capacity. In the present example, it is assumed that the land use comprises 100% olive orchards. The scenario identification procedure is thus restricted to soil properties and land use is taken as a constant. In order to ensure consistency with the approach used by PRZM, it is recommended to classify soils according to hydrological soil groups as they were originally proposed by the US Soil Conservation Service (see Table A1.6).

Table A1.6. Hydrological soil groups according to the classification of the US SCS

Soil Group	Description
A	Soils having a low runoff potential and high infiltration rates even when thoroughly wetted. They consist chiefly of sands and gravels that are deep, well drained to excessively drained and have a high rate of water transmission (> 0.3 in/hr)
B	Soils having moderate infiltration rates when thoroughly wetted and consist chiefly of soils that are moderately deep to deep, moderately well drained to well drained and have moderately fine to moderately coarse textures. These soils have a moderate rate of water transmission (0.15 – 0.3 in/hr)
C	Soils having low infiltration rates when thoroughly wetted. They consist chiefly of soils having a layer that impedes downward movement of water and soils of moderately fine to fine texture. These soils have a slow rate of water transmission (0.05 – 0.15 in/hr)
D	Soils having a high runoff potential. They have very low infiltration rates when thoroughly wetted and consist chiefly of clay soils with a high swell potential, soils with a permanent high water table, soils with a claypan or clay layer at or near the surface, and shallow soils over nearly impervious material. These soils have a very low rate of water transmission (0 – 0.05 in/hr)

Source: Engineering Technical Note – Estimating Runoff for Conservation Practices, Ref. No. 210-18-TX5, Soil Conservation Service. U.S. Dept. of Agriculture, 1990

A 'best-guess' indicator for hydrological soil groups seems to be the dominant soil texture class. Organic carbon contents provide additional indication about the relative runoff vulnerability of soils that belong to the large group of medium to medium fine textured soils. Both texture and organic carbon contents are given as classes in the EU soil map (see Table A1.7).

Table A1.7. Proposed classification of runoff vulnerability

Runoff vulnerability	Soil texture	Organic carbon
Low (group A)	Text1 or 2 = 1	Any
Medium (group B)	Text1 or 2 = 2	Low to high
High (group C)	Text1 or 2 = 2, 3	Medium fine text. = very low, Fine text. = any
Very high (group D)	Text1 or 2 = 3, 4	Any

Soil texture classes
1 = clay < 18 % and sand > 65 % (coarse)
2 = 18 % < clay < 35 % and sand > 15 %; or clay < 18 % and 15 % < sand < 65 % (Medium)
3 = clay < 35 % and sand < 15 % (Medium fine)
4 = 35 % < clay < 60 % (Fine)
5 = clay > 60 % (Very fine)

Organic carbon content in topsoil
High = > 6.0 %
Medium = 2.1 – 6.0 %
Low = 1.1 – 2.0 %
Very low = < 1.0 %

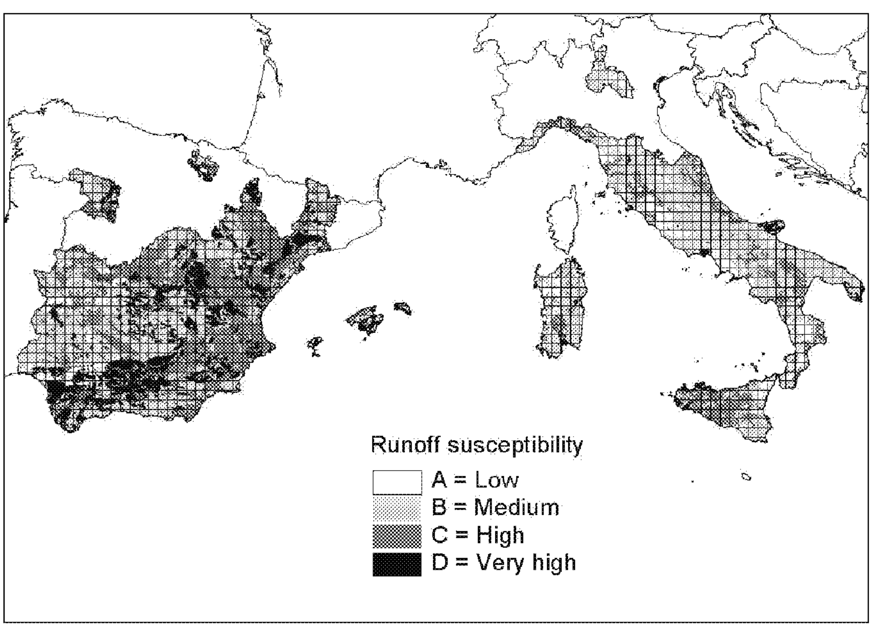


Figure A1.12. Runoff susceptibility based on soil texture and organic carbon content.

A1.5 General considerations about the selection of candidate scenario locations for Step 4 assessments

The approach described aims to support the identification of additional scenario areas in order to establish a range of PECsw on the regional scale. There are a number of uncertainties related to the proposed methods. Nevertheless, when using generally available GIS data sets the derivation of additional surface water scenarios is transparent and can be reproduced with the same databases.

In any case it is crucial to follow 'Good Modelling Practice' in the derivation of new modelling scenarios. This implies that all assumptions are made transparent and are accompanied by an assessment of the potential impact on modelling results.

An unbiased selection of candidate scenario locations starts with the selection of target climate vulnerabilities (*e.g.* 90th, 75th, 50th percentile climate vulnerabilities). In a second step, a suitable soil vulnerability is added to the climate scenario. Current GIS technology allows for a comprehensive summary of individual data layers and can therefore be used to justify the selection of a specific climate grid cell (Table A1.9). The above-mentioned percentile values are recommended target percentiles. Nevertheless a risk assessor should also consider scenarios in the major cropping areas of the target crop, even in cases when the respective areas are not represented by the above mentioned target percentiles. In the present example the most prominent cropping area for olives is the province of Jaén in Spain, which exhibits a climate vulnerability between the 75th and 25th percentile for drainage and runoff losses. As a consequence, it seems appropriate to select at least one scenario in that province. The calculated percentile is subsequently used to assess the total vulnerability of the scenario.

Table A1.8. Considerations for the selection of candidate scenarios

Scenario	Climate vulnerability	Soil vulnerability
1	Worst case	Worst case
2	Medium case	Worst case
3	Worst case	Medium case
4	Medium case	Medium case
5	No consideration of vulnerabilities Scenario location in the most important cropping area	

Table A1.9. Example summary of climate vulnerabilities

MARS Climate grid No	Elevation (m)	Spring temp. (℃)	Autumn temp. (℃)	Admin. Unit	Olives (ha)#	Recharge (mm)	Annual avg. temp (℃)	Percentile Recharge (%)	Percentile Temp. (%)	Percentile Climate (%)
.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
.....	37	17.5	20.0	Cadiz	14816	305	18.9	0.64	0.94	91.4
.....	16	17.5	20.0	Malaga	111683	305	18.9	0.64	0.94	91.4
.....	70	17.5	20.0	Cadiz	14816	292	18.9	0.62	0.94	90.9
.....	46	17.5	20.0	Cadiz	14816	292	18.9	0.62	0.94	90.9
.....	196	15.7	20.0	Trapani	17500	420	18.3	0.86	0.78	90.4
.....	203	17.2	19.8	Malaga	111683	320	18.7	0.66	0.92	89.7
.....	292	14.2	18.3	Reggio Calabria	57542	613	16.8	0.98	0.38	89.6
.....	5	17.7	20.1	Sevilla	180876	256	18.9	0.53	0.95	89.5
.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
.....	40	17.2	19.8	Huelva	29006	238	18.5	0.48	0.86	76.2
.....	197	14.5	18.2	Salerno	39011	459	16.9	0.89	0.41	76.0
.....	94	15.0	17.3	Genova	3780	546	16.5	0.93	0.32	76.0
.....	28	17.1	19.7	Cadiz	14816	251	18.4	0.52	0.83	76.0
.....	38	14.8	17.1	Imperia	6462	549	16.3	0.93	0.31	75.8
.....	60	17.5	19.8	Sevilla	180876	195	18.7	0.34	0.92	75.6
.....	0	16.4	21.0	Siracusa	11300	133	19.3	0.20	0.97	75.4
.....	71	14.7	18.1	Caserta	8530	445	16.9	0.88	0.42	75.0
.....	57	17.2	19.6	Huelva	29006	245	18.4	0.51	0.83	74.9
.....	292	14.6	18.2	Cosenza	52180	425	17.0	0.86	0.45	74.9
.....	87	14.8	18.6	Catanzaro	53550	370	17.3	0.82	0.52	74.9
.....	17	16.4	21.0	Siracusa	11300	129	19.3	0.19	0.97	74.6
.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
.....	341	15.9	18.1	Cáceres	75085	218	17.5	0.41	0.60	50.1
.....	268	15.9	18.2	Badajoz	174985	239	17.3	0.49	0.52	50.1
.....	73	17.8	20.7	Almeria	11690	15	19.5	0.02	0.99	50.0
.....	60	17.8	20.7	Almeria	11690	15	19.5	0.02	0.99	50.0
.....	1192	7.8	9.4	Lleida	35249	826	9.0	0.99	0.01	50.0
.....	1279	7.2	8.9	Lleida	35249	1632	8.6	0.99	0.01	50.0
.....	333	16.1	18.0	Cáceres	75085	220	17.5	0.41	0.59	49.9
.....	228	16.0	18.4	Huelva	29006	231	17.3	0.46	0.53	49.6
.....	88	14.8	18.3	Sassari	11857	258	17.0	0.54	0.46	49.6
.....	29	14.9	18.6	Lecce	83363	222	17.4	0.42	0.57	49.6
.....	0	14.5	17.9	Bari	126961	275	16.8	0.60	0.39	49.6
.....	71	14.5	17.9	Brindisi	62950	275	16.8	0.60	0.39	49.6
.....	102	14.4	17.5	Livorno	3900	335	16.3	0.69	0.31	49.5
.....	86	15.8	20.1	Agrigento	24800	127	18.4	0.18	0.81	49.5
.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....

Total olive area in administrative unit

Table A1.9 provides a summary of climate grid cells that express a particular climate vulnerability. In a final step, it is always required to check whether the target crop – in this case olives - actually occurs in that grid cell. For practical reasons, this final and detailed reality check cannot be performed in an earlier stage of the assessment which starts at the European scale and is subsequently refined on the local scale.

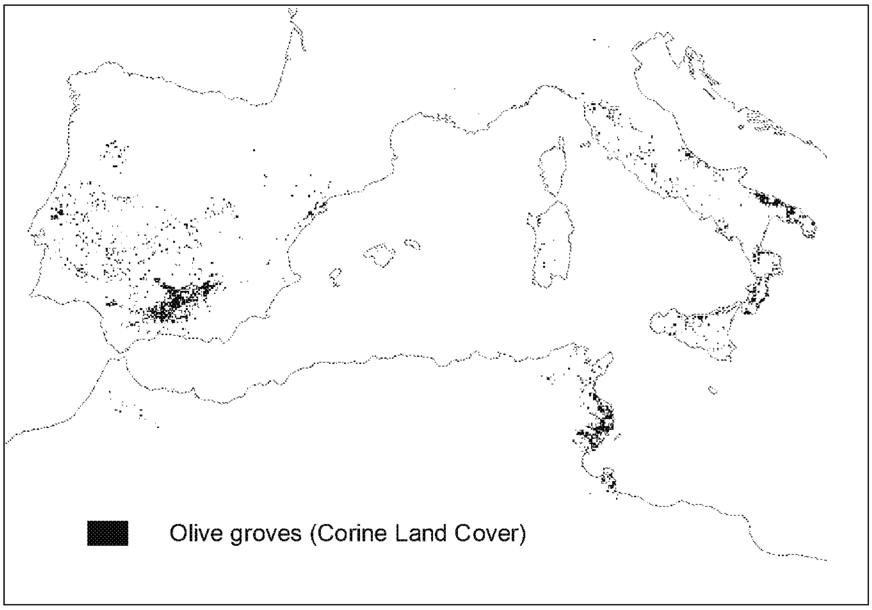


Figure A1.13. Olive groves in the Mediterranean Region (source: Corine Land Cover, 1998).

The most accurate information on soil properties is given in the 'Estimated Profile Database' (est.hor), which contains soil profile information for a number of soils. Unfortunately, some countries provide only a small number of agricultural soil profiles in the 'Estimated Profile Database'. A research project is currently on-going which aims to provide agricultural profiles for all soil typological units in the EU soil map. Once this additional information is available, the accuracy of Step 4 evaluations will increase significantly (SPADE2 project; Hollis et al., 2002)

In general, it is recommended to give preference to data stored in the 'Estimated Soil Profile Database when parameterizing a scenario. However, in cases where no information is available, a generic soil profile has to be derived by means of the diagnostic properties of FAO soil types (FAO, 1994), the information provided at the level of soil typological units (stu.dbf), and general knowledge about agronomic and landscape factors that determine specific soil characteristics.

Other parameters such as cropping dates and crop growth parameters should preferably be taken from a representative FOCUS scenario.

A1.6 Determining the applicability of Step 4 scenarios

After the identification of candidate scenario locations based on consideration of the geographic extent of the crop, rainfall, temperature and soil drainage and runoff potential, it is appropriate to identify similar areas located within the European Union to facilitate the interpretation and regulatory acceptance of the new scenarios.

From a risk assessment perspective, the new scenarios represent all agricultural areas with similar or lower levels of vulnerability. It is important to recognise that the geographic extent of a scenario should be compared with the spatial distribution of the target crop and not with the area of a country or the total extent of arable land within a country. In the present example, the area with a similar or lower vulnerability for pesticide losses via drainflow and runoff would be characterised by the co-occurrence of the following properties:

- Area used for olive production
- Soils with similar or lower vulnerability for runoff
- Soils with similar or lower vulnerability for leaching.
- Climatic zones with similar or lower vulnerability based on rainfall and temperature

Finally, a representative area can be determined for each scenario. 90^{th} percentile worst-case scenarios are representative of a large part of the total olive area since it is assumed that only 10% of the total cropping area is more vulnerable. However, when visualising the geographic extent of 90th percentile scenarios on maps, the resulting area can become small when the crop itself is grown in a very small region.

Acknowledgment

Adrian Gurney (RCC Ltd., Itingen/CH) provided valuable support in the derivation of the method to quantify the vulnerability of modelling scenarios.

References

Burgoa B and R.D. Wauchope (1995): Pesticides in runoff and surface waters. In: T.R. Roberts and P.C. Kearney (eds.). Environmental Behaviour of Agrochemicals. John Wiley and Sons: 221-255.

Corine Land Cover (1998): Digital data on land use in Europe based on remote sensing. Data provided in a 250 x 250 m resolution. European Topic Centre on Land Cover. European Environment Agency. Kiruna.

DVWK (1985) Niederschlag – Starkregenauswertung nach Wiederkehrzeit und Dauer. Regeln zur Wasserwirtschaft 124/1985. Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e.V. [German publication, includes many references to relevant publications in English]

ESGDB (1998): European Soil Geographical Database. (Version 3.2.8.0). European Soil Bureau.

FAO (1994): World Reference Base for Soil Resources. International Society of Soil Science/ International Soil Reference and Information Centre/ Food and Agriculture Organisation of the United Nations. Wageningen/ Rome.

FAO (1995): The Digital Soil Map of the World – Version 3.5. Food and Agriculture Organisation of the United Nations. Roma.

Gumbel E.J. (1958): Statistics of the Extremes. Columbia University Press. New York. 375 p.

Hollis J. (2002): Creation of Version 2 of the Soil Profile Attribute Database for Europe (SPADE-2)

Huber A., Bach M. and H.G. Frede (1998): Modelling pesticide losses with surface runoff in Germany. The Science of the Total Environment 223: 177-191.

ISTAT (1998): Istituto Nazionale di Statistica. Olive production area per provinzia.

MARS (1997): MARS Meteorological Database. Description of products. JRC EU Commission. Ispra.

Rudloff, W. (1981): World Climates – with tables of climatic data and practical suggestions. Books of the Journal Naturwissenschaftliche Rundschau. Wissenschaftliche Verlagsgesellschaft Stuttgart. 632 p.

SCEES (2000) recensement agricole 2000, Service central des enquêtes et études statistiques (Scees) du ministère de l'agriculture et de la pêche.

SCS (1990): Engineering Technical Note – Estimating Runoff for Conservation Practices, Ref. No. 210-18-TX5, Soil Conservation Service. U.S. Dept. of Agriculture, 1990

Weiss L.L. (1964): Ratio of true to fixed-interval maximum rainfall. ASCE J. Hydraul. Div HY1. January 1964.

A2 ILLUSTRATION OF A POSSIBLE APPROACH TO REFINING EXPOSURE USING CATCHMENT-LEVEL MODELLING – FUNEN

The FOCUS Landscape and Mitigation working group addressed possible refinements to risk assessment to support listing on Annex I and for national registration procedures. This example is for a refinement specific to a particular usage scenario, but the broad approach is generic. The example is intended to be illustrative; it does not replicate a regulatory submission (e.g. the level of detail and justification of decisions are both less than would be required) and is not intended to be prescriptive. A detailed opinion of the illustration is available from PPR (2006), including information on additional requirements and/or considerations where the broad approach is used for a regulatory submission.

Use Profile

Product 'WEEDOWASTE' is used in the pre-emergence control of broad leaf weeds in winter barley and winter wheat. Usage rate is proposed as 1.6 kg a.s./ha. Marketing restrictions imposed from within the registrant company preclude the opportunity to consider buffer zones to reduce aquatic exposure via spray drift.

Problem Summary

- Step 1 and 2 calculations indicated potential concerns associated with acute risk to fish and risk to algae.
- More sophisticated exposure assessment modelling employing the FOCUS Surface Water Framework at Step 3 suggest that risk to fish is acceptable within relevant scenarios.
- However, Step 3 modelling highlights potential concern surrounding risks to algae associated with a product in scenario D4 (stream scenario only – pond scenario passes).
- Opportunities for introducing mitigation strategies to reduce apparent drainflow risk in this drainage scenario within the FOCUS framework at Step 4 are very limited.
- Although no-spray buffer zones may provide an expedient means of incorporating required mitigation, marketing restrictions imposed from within the registrant company preclude the opportunity to consider these drift mitigation options.
- Strategies for demonstrating more realistic exposure profiles must address the specific concerns summarised above that are associated with proposed Danish GAP and usage practices.

Strategy

- Opportunity to introduce drainage and drift mitigation options are severely limited. As a consequence, the strategy must focus instead on the generation of more sophisticated and realistic assessments of exposure than are provided by the FOCUS framework at Step 3.
- The strategy is based upon carrying out more sophisticated, catchment-level modelling within a well-characterised site with similar agricultural, hydrological and climatic conditions to scenario D4.

- Modelling should be robust and assumptions regarding proximity of crop and surface water and density and timing of use within the catchment should, at least initially, be relatively conservative.
- As a component of this approach it will be necessary to demonstrate to what extent is the research catchment (cropping, soils and surface waters) representative for this type of cropping for Funen and Denmark.

A2.1 Profile of Active Substance and FOCUS SW Modelling

Product 'WEEDOWASTE' is used in the pre-emergence control of annual grasses and broad-leaved weeds in winter barley and winter wheat. Usage rate is 1.6 kg a.s./ha. Marketing restrictions imposed from within the registrant company preclude the opportunity to consider no-spray buffer zones to reduce aquatic exposure via spray drift.

A profile of environmental fate and ecotoxicology characteristics is provided below:

Physico chemical parameters	
Molecular weight	300 g/mol
Solubility in water	53 mg/l at pH 7 and 20°C
Vapour pressure	3.15×10^{-6} Pa
Degradation parameters of the substance	
Degradation rate or half life in top soil	DT_{50} = 16.1 d at 20°C and pF 2.0
Sorption parameters	
K_{oc}-value	K_{oc} = 125 dm^3/kg
Exponent of the Freundlich Isotherm	0.9
Water-sediment dissipation	
Surface water dissipation half-life	DT_{50} = 17 d
Sediment dissipation half-life	DT_{50} = 0.5 d

The following ecotoxicology profile is used in the risk assessment:

Fish LC_{50} (96 h static mortality):	9.0 mg/l
Aquatic invertebrate EC_{50} (48 h static immobilisation):	507 mg/l
Algae EC_{50} (72 h growth):	0.081 mg/l
Lemna EC_{50} (10 d):	31.0 mg/l
Fish NOEC (28 d ELS)	4.5 mg/l
Aquatic Invertebrate NOEC (21 d repro)	300 mg/l

A2.1.1 Simulation Results – FOCUS Step 1 and 2

Maximum PEC values for WDC756 at Step 1 and 2 were 471.86 and 201.43 ∝g/l, respectively. These result in the following TER profiles:

	Step 1	Step 2
Fish LC_{50} (96 h static mortality):	19	45
Aquatic invertebrate EC_{50} (48 h static immobilisation):	1074	2517
Algae EC_{50} (72 h growth):	0.17	0.40
Lemna EC_{50} (10 d):	133	228
Fish NOEC (28 d ELS)	9.5	22
Aquatic Invertebrate NOEC (21 d repro)	636	1489

Accordingly, after a Step 1 and 2 exposure assessment, risks to fish and algae cannot be discounted and, as a consequence further assessments at Step 3 are necessary.

A2.1.2 Simulation Results – FOCUS Step 3

Within scenario D4 there are two water bodies, a pond and a stream. The results of simulations considering drift and drainage loadings into each system are summarised below:

	D4 Pond	D4 Stream
Maximum PEC:	3.153 ∝g/l	8.771 ∝g/l
48 h TWA PEC:	3.147 ∝g/l	5.384 ∝g/l
96 h TWA PEC:	3.133 ∝g/l	5.089 ∝g/l
7 d TWA PEC:	3.121 ∝g/l	4.622 ∝g/l
14 d TWA PEC:	3.072 ∝g/l	3.440 ∝g/l
21 d TWA PEC:	2.984 ∝g/l	2.741 ∝g/l
28 d TWA PEC:	2.865 ∝g/l	2.243 ∝g/l

These maximum PEC values result in the following TER profiles:

	D4 Pond	D4 Stream
Fish LC_{50} (96 h static mortality):	2854	1026
Aquatic invertebrate EC_{50} (48 h static immobilisation):	160799	160799
Algae EC_{50} (72 h growth):	26	9.2
Lemna EC_{50} (10 d):	9933	6707
Fish NOEC (28 d ELS)	1281	513
Aquatic Invertebrate NOEC (21 d repro)	85397	34204

Accordingly, after a Step 3 exposure assessment, risks to fish have now been successfully addressed. However, concerns surrounding exposure to algae remain and, as a consequence further assessments at Step 4 are necessary.

A2.2 Methodology for Step 4 Assessment

A2.2.1 Strategy at Step 4

The strategy for refinement of the risk assessment at Step 4 is based upon provision of more sophisticated, catchment-level modelling within a well-characterised site with similar agricultural, hydrological and climatic conditions to scenario D4.

A2.2.2 Site Selection

The selection of model areas was based on several criteria:

[1] The catchment should be 1st order, with at least 1 km of stream,

[2] It should represent the common soil types used for agriculture on Funen (and in Denmark), where the pesticide is to be used,

[3] It should be dominated by agriculture,

[4] The agricultural systems of the areas should be considered ”typical”,

[5] Opportunities to draw upon data from a well-characterised research site.

The most obvious candidates as study catchments were the catchments belonging to the Danish monitoring programme, with a set of basic data and measurements of precipitation, streamflow and several other parameters since 1989. One sandy loam monitoring catchment exists on Funen.

In order to ensure that the selected catchment is reasonably comparable to the D4 scenario, the local data are reviewed. It is also documented that this small catchment represents many of the features of the island of Funen. The catchment is 4.4 km^2 in area. This catchment is 4.4 times largerr than the upstream catchment simulated in the FOCUS Surface Water stream scenario. However, it is considered to provide a realistic and robust basis for assessing behaviour in a system dominated by relatively small, shallow water bodies and heavily influenced by drainage responses to rainfall.

A2.2.3 Climate data

The D4 scenario represents areas with 660 mm rainfall. The selected year for FOCUS calculations, though, has 692 mm of rainfall. It is expected that the figures are uncorrected values. In Denmark, rainfall data are corrected upwards with monthly values. However, the correction values have changed over time – the factors used to be in the order of 16 % on an annual basis, while it is now around 21 % of the uncorrected rainfall.

The monitoring catchment was estimated to have an average precipitation of 704 mm during the period 1961-1990 (old correction factors). With respect to rainfall data, the monitoring catchment appears to be in the right range. In actual fact, during the monitoring period, the rainfall was higher (see Table A2.1).

Through comparisons of the period 1991-2000 with longer time series, the following observations (Henriksen and Sonnenborg, 2003) should be noted:

1. The period 1991-2000 is characterised by considerable variation between wet and dry years relative to the long-term weather record. This period is characterised by a single very dry year (1996) and three very wet years (1994, 1998 and 1999). The precipitation occurring within the dry year has a recurrence interval of about 50 years (2 % fractile) compared with the long-term record. The three wet years are the wettest in the whole historical time series.

2. The average levels of rainfall and runoff for the period 1991-2000 provide a 10-year period with the largest registered rainfall and runoff.

3. The winter precipitation in the period 1991-2000 was greater than the winter precipitation for the period 1961-1990. In general, the winter precipitation has since 1961 been higher than in the preceding period.

It is expected that the MARS dataset is uncorrected, which explains part of the difference between rainfall estimates for D4 and the monitoring catchment.

Table A2.1. Water balance for the sandy loam catchment (new correction factors)

Year	Bolsmose (the sandy loam catchment)	Årslev (research station on Funen)	
	Precipitation, mm	Potential evaporation, mm	Measured runoff at the outlet or the catchment, 1000m^3
1989	681	573	567
1990	961	613	887
1991	818	573	1015
1992	811	634	812
1993	964	549	1292
1994	1159	610	1941
1995	712	629	1362
1996	631	572	237
1997	720	639	338
1998	1036	538	1255
1999	1091	613	1867
2000	884	553	1094

A2.2.4 Percolation

It is predicted that the percolation should be 100-200 mm/year for the D4 scenario. This is judged to be lower than what is found for the monitoring catchment and Funen in general. Whether this is due to the lack of correction factors on rainfall or an unrealistically low estimate in FOCUS is not clear.

A2.2.5 Soil types

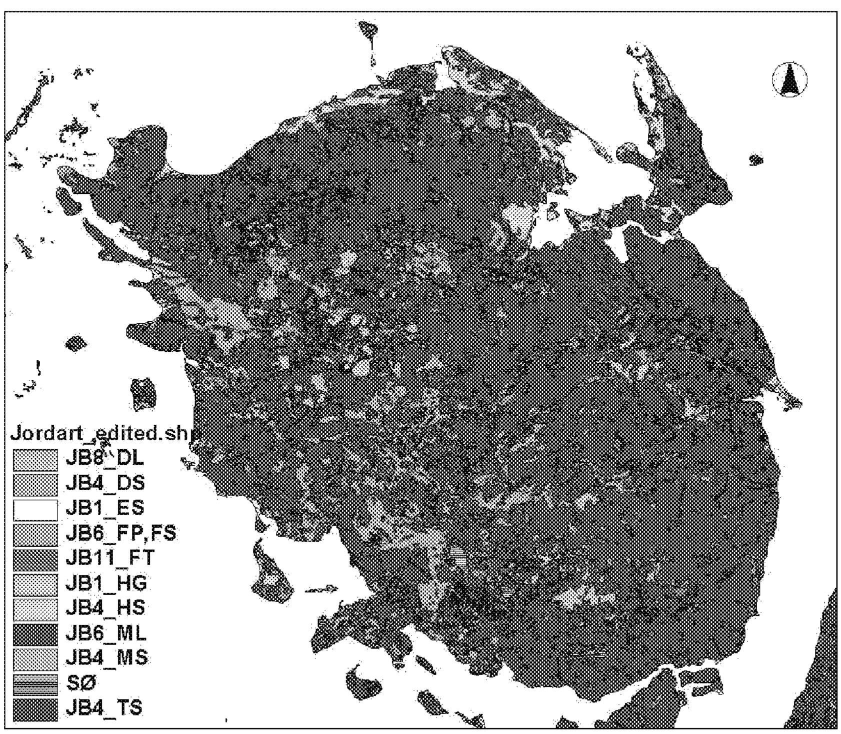
The catchment was selected with the purpose of representing the moraine clay soils of Sealand, Funen and East Jutland (soil type JB5 and JB6[1]).

[1] JB1: 0-5% clay, 0-20% silt, 0-50% fine sand, 75-100% sand in total, <10% humus
JB2: 0-5% clay, 0-20% silt, 50-100% fine sand, 75-100% sand in total, <10% humus
JB3: 5-10% clay, 0-25% silt, 0-40% fine sand, 65-95% sand in total, <10% humus
JB4: 5-10% clay, 0-25% silt, 40-95% fine sand, 65-95% sand in total, <10% humus
JB5: 10-15% clay, 0-30% silt, 0-40% fine sand, 55-90% sand in total, <10% humus
JB6: 10-15% clay, 0-30% silt, 40-90% fine sand, 55-90% sand in total, <10% humus
silt defined as being between 2 and 63 microns

The D4 scenario has a soil A horizon with 12 % clay, 37 % silt and 51 % sand. In the Danish classification system it belongs to the type JB6.

For the sandy loam catchment (see Table A2.3), the clay content of the A-horizon lies between 14.8 and 18.6 % (JB6-7). The B-horizon is generally more clayey, but specific horizons may lie in the range from 15.9 to 25.9 % clay (sampled in six profiles). The C-horizon may be similar to the B-horizon (19-22 % clay, three of the six profiles), more silty (14.4 % clay, 62.5 % silt), more clayey (30.5 % clay) or more sandy (8.2 % clay, 72.6 % sand). The lower horizons are generally slightly more sandy in the D4-horizon than in the catchment, see Table A2.3 and A2.4.

Figure A2.1. Classes of base material on Funen prepared from textural data and geological maps (1:200.00, supplemented by 1:25.000). The soil type of relevance is named as JB6_ML (moraine clay) and dominates the island.



The D4 scenario, the monitoring catchment and Funen in general (see Figure A2.1) are dominated by moraine clay. The texture of the soil type in the monitoring catchment is slightly heavier than for the D4 sceanrio.

The soils are, to a large extent, drained. The soil types JB5, JB6 and the slightly heavier type with 15-25 % clay (JB7) together make up 30 % of the soil types in Denmark.

A2.2.6 Overall Land Use

The selected catchment is dominated by agriculture and is therefore likely to represent areas of relevance when considering exposure potential. Approximately 89% of the monitoring catchment is used for agriculture, 2% is forest and 9% is villages and roads. The catchment is therefore representative of intensive agricultural areas in Denmark.

The D4 scenario covers winter and spring cereals, winter and spring rape, sugarbeets, potatoes, field beans, vegetables, maize, apples, grass and alfalfa. All the expected crops except alfalfa are grown in the two areas. The crop selection thus lies within the expected range for the D4 scenario.

Table A2.2. Land under agricultural management in Funen and the sandy clay catchment (figures from the County of Funen and NERI) for selected years.

	Funen	Sandy clay catchment
Year	2000	1997
Spring cereals	18.0	21.2
Winter cereals	44.2	43.8
Seeds	11.0	21.0
Pulses	2.4	0.03
Root crops	7.1	2.10
Grass and green fodder*	10.4	9.0
Fallow	2.48	-
Other	4.1	-
Plantation and forest**	0.3	2.9
Total	**100**	**100**
Continuous grass (untreated)	?	1.25

* includes maize
** includes apple trees

A2.2.7 Hydrology of water bodies

The stream flow characteristics correspond to the soil types. The moraine clay catchment is dominated by drain flow. Base flow is negligible, and the flows during summer are very small.

A study regarding pond types was commissioned to the Institute of Geography. Two types of pond were described:

- One type on moraine soils where the pond is caused by low conductivity of the soil and where the water level drops during summer. The primary groundwater lies below the bottom of the pond.

- One type, which is caused by groundwater intercepting the surface. This type is more common on sandier soils.

Two features make the moraine clay catchment "low risk" with respect to spray drift: a considerable length of the stream is piped and along part of the open stream, trees provide a barrier between the agricultural land and the stream. However, in the calculations done for registration purposes, the stream is opened and only the effect of the buffer width is considered. No special effect is assumed to account for the fact that trees are present in parts of the catchment. A schematic of the catchment is provided in Figure A2.2.

Table A2.3. Soil texture and measured retention properties for the sandy clay catchment.

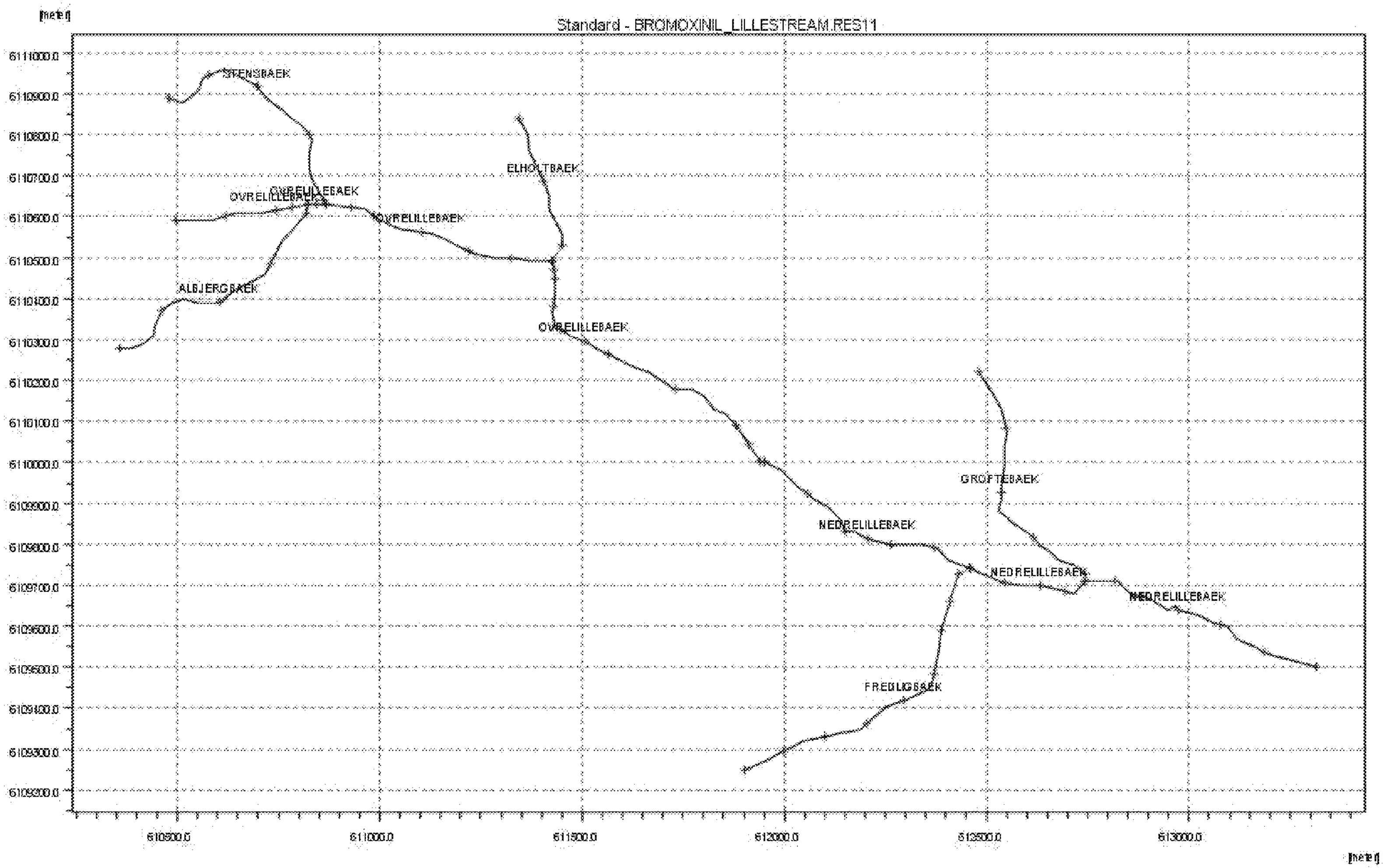
		Humus	Clay	Silt	Silt	Fine sand	Coarse sand	Vol.weight	Porosity	Water content, volume-percent			
		%	<2µm	2-20 µm	20-63 µm	63-200 µm	200-2000 µm	g/cm^{3}*	*	pF 1*	pF 2*	pF 3*	pF 4.2
1	Ap	1.7	16.7	13.3	10.7	31.2	26.4	1.65	37.9	34.8	28.5	23.9	13.1
	A2	2	15.9	15.1	10.2	28.6	28.2	1.68	36.6	33.6	27.5	22.1	13.3
	B	1.5	19.8	14.2	11.3	29.2	24.0	1.63	38.4	36.9	29.2	23.0	14.6
	C	0.2	19.7	14.3	10.2	27.6	28.0	1.71	35.4	34.6	29.8	22.2	13.6
2	Ap	1.7	18.6	11.4	9.5	30.2	28.6	1.75	34.0	31.5	27.5	21.1	15.2
	B1	0.6	25.9	13.1	9.4	27.6	23.4	1.74	34.4	32.8	30.2	24.7	18.3
	B2	0.3	21.7	13.3	11.1	28.0	25.6	1.69	36.3	31.8	28.7	24.0	14.9
	C	0.2	22.7	13.3	9.8	27.8	26.2	1.70	35.7	33.4	31.0	26.2	15.5
3	Ap	2.0	15.4	12.0	10.2	30.8	29.6	1.70	35.8	33.4	28.4	23.6	13.1
	A2	1.1	21.6	20.4	6.1	25.0	25.8	1.53	42.3	33.1	25.2	18.4	14.2
	B	0.4	23.6	13.4	9.0	26.6	27.0	1.67	37.0	31.6	27.8	22.3	15.9
	C	0.2	19.4	11.6	9.6	27.0	32.2	1.74	34.4	30.4	27.5	23.2	13.7
4	Ap	3.1	17.7	14.1	11.9	26.8	26.2	1.43	45.9	41.2	36.6	30.6	13.5
	B1	0.4	24.8	15.2	15.4	24.6	19.6	1.67	36.9	31.4	26.3	21.6	16.7
	B2	0.2	21.6	13.4	11.2	25.0	28.6	1.73	34.6	33.9	28.6	23.3	15.1
	C	0.1	14.4	9.6	52.9	16.8	6.2	1.65	37.7	37.6	35.9	29.4	9.9
5	Ap	2.1	14.8	15.2	8.1	32.2	26.8	1.42	46.4	41.2	25.0	15.1	10.8
	A2	2.0	14.8	13.2	11.2	31.0	27.4	1.58	40.4	37.0	26.6	17.3	11.8
	B	0.5	24.8	12.2	9.7	29.2	23.6	1.61	39.3	39.2	31.4	22.7	16.2
	C	0.3	30.5	11.5	8.9	25.2	23.6	1.64	38.1	37.6	34.1	27.2	19.7
6	Ap	2.1	17.0	21.0	16.1	23.4	20.4	1.38	48.0	44.0	28.5	20.7	11.5
	Bx	0.8	21.7	15.3	9.0	24.4	28.8	1.79	32.4	31.6	29.1	25.3	16.4
	Bt	0.3	20.5	11.5	9.3	27.6	30.8	1.67	37.1	36.5	29.8	21.9	13.9
	C1	0.1	4.9	0.5	1.0	14.2	79.3	1.52	42.5	36.1	7.5	4.2	3.8
	C2	0.1	14.4	8.6	9.1	32.0	35.8	1.82	31.5	30.1	24.6	19.7	10.8
	Cr	0.0	8.2	7.3	11.9	39.4	33.2	1.62	38.8	34.9	18.4	7.8	5.9

*average of 3 values

Table A2.4. Soil Texture and measured retention properties for the D4 scenario

		Humus %	Clay <2∝m	Silt 2-50 ∝m	Sand 63-2000 ∝m	Vol.weight g/cm^3*	Porosity *
1	Ap	1,4	12	37	51	1,48	42
	Eb	0,8	13	17	70	1,65	36
	Ebg	0,3	15	18	67	1,65	36
	Btg	0,2	28	39	33	1,76	33
	BCg	0,1	10	27	73	1,80	30

Figure A.2.2. Scematic of the Funen catchment



A2.3 Simulation Results for Step 4 Assessment

The same data that were employed within FOCUS Step 1-3 simulations were used to set up the PESTSURF model. Where appropriate, these input data were supplemented in order to meet the input requirements of the PESTSURF model. PESTSURF (Styczen et al., 2004a, 2004b and 2004c) is a catchment model based on the hydrological modelling system MIKE SHE (Abbott et al., 1986; Refsgaard and Storm, 1995). The modelling system is applied to the sandy loam catchment and calibrated to fit measured groundwater levels and stream flow. PESTSURF is further described in Volume 2, Section 2.1.3 of this report.

Simulations were established based upon the sandy loam catchment. Simulated usage was consistent with both previous FOCUS modelling and local practices, with one major difference. In the simulation it is assumed that all agricultural land in the catchment is sprayed within half an hour– not only 20 % of the upstream area as in the FOCUS modelling exercise. Results of these simulations are summarised in a series of graphs and tables below.

Figure A2.3.Concentration profile for 'WEEDOWASTE' along the upper part of the main stream.

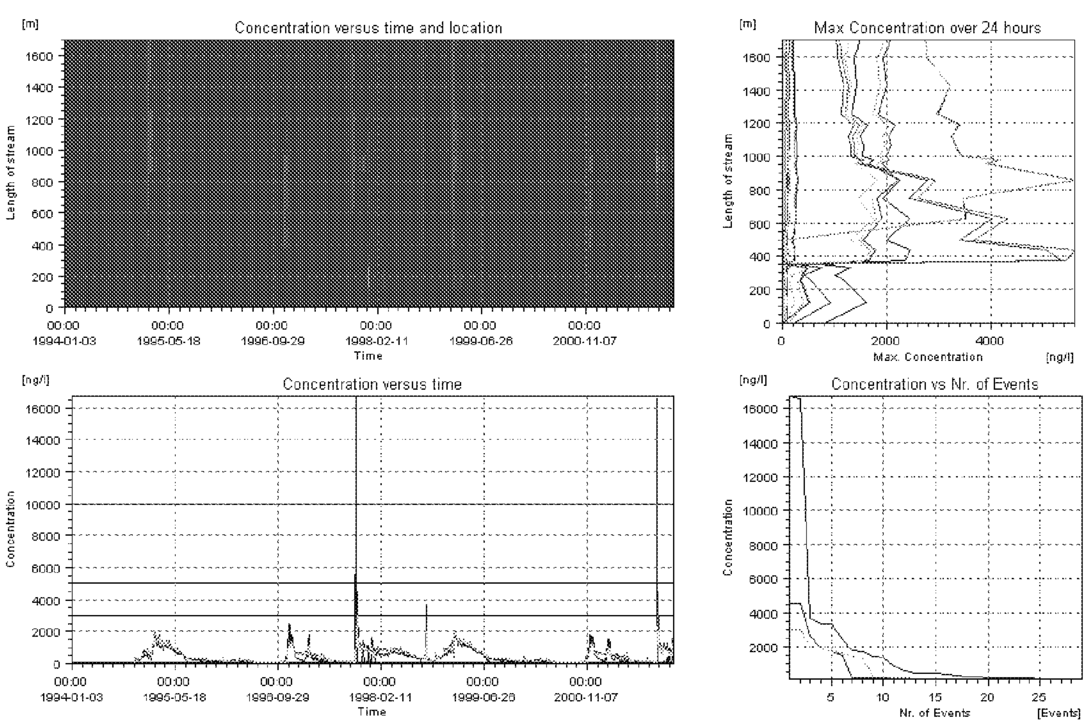
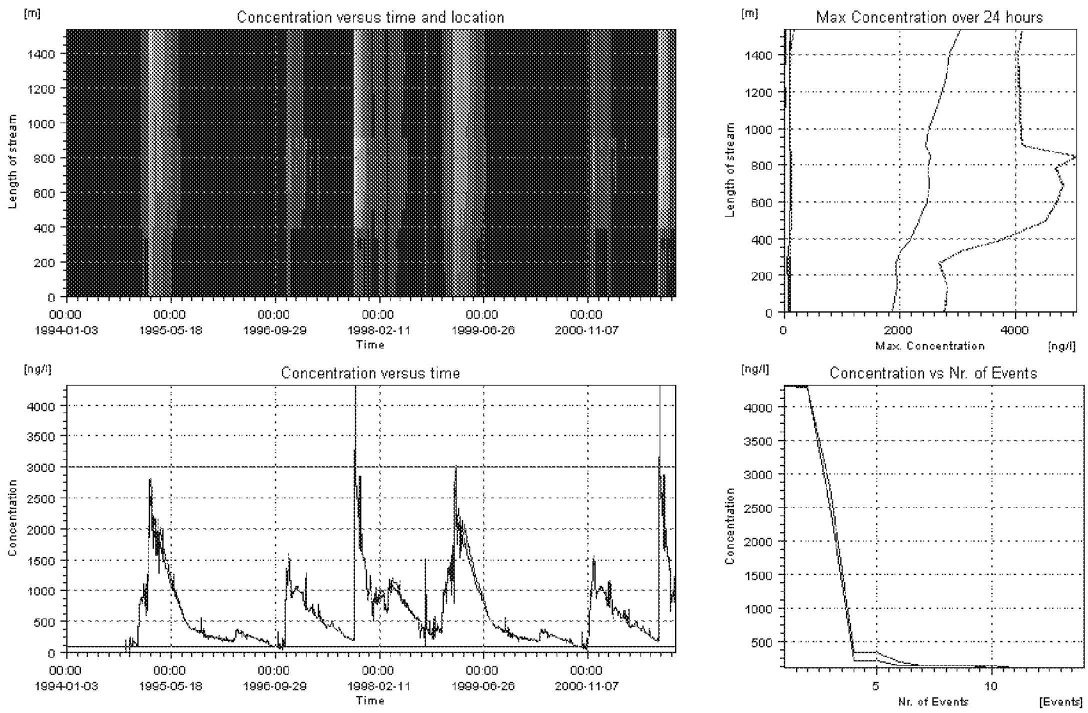


Figure A2.4.Concentration profile for 'WEEDOWASTE' along the lower part of the main stream.



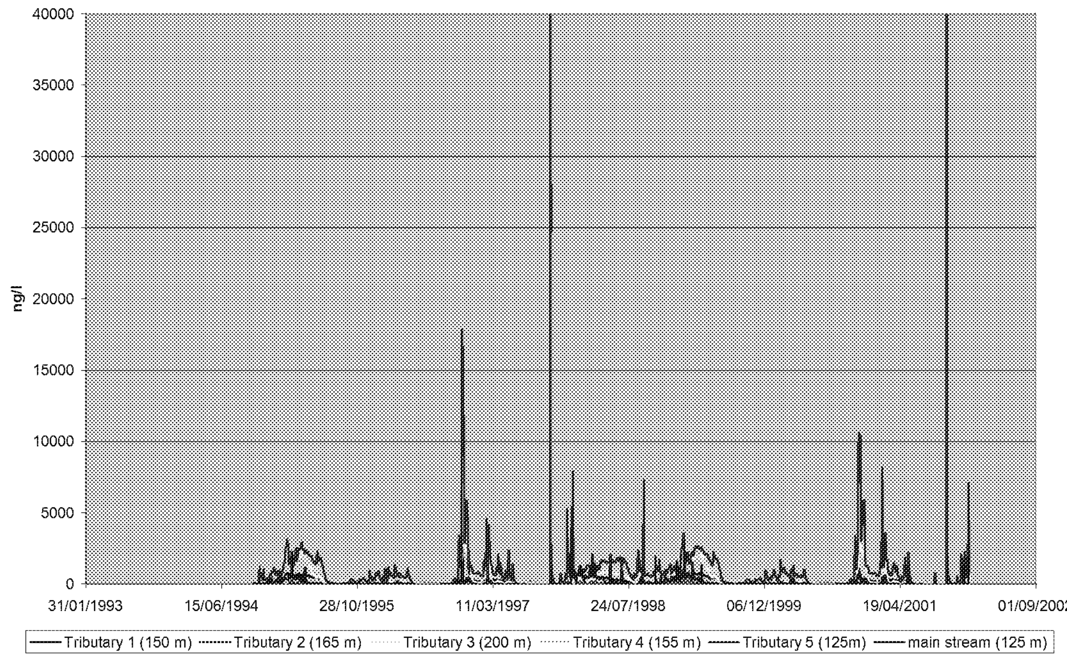
The first four simulation years were run as an equilibration period. The evaluation is carried out on the last four years of the simulation period. The plots in Figures A2.3 and A2.4 show a major event during the last simulation year which is a dry year. The highest concentrations are found upstream. Figure A2.5 illustrates the concentrations at selected points in the stream system, including five tributaries to the sandy clay catchment. Very high concentrations are found in the tributaries that are smaller in scale and often almost dry systems.

Table A2.5. Maximum concentrations for each of the stream points shown in Figure A2.4 and the date in the evaluation period (1998-2001) that it occurs.

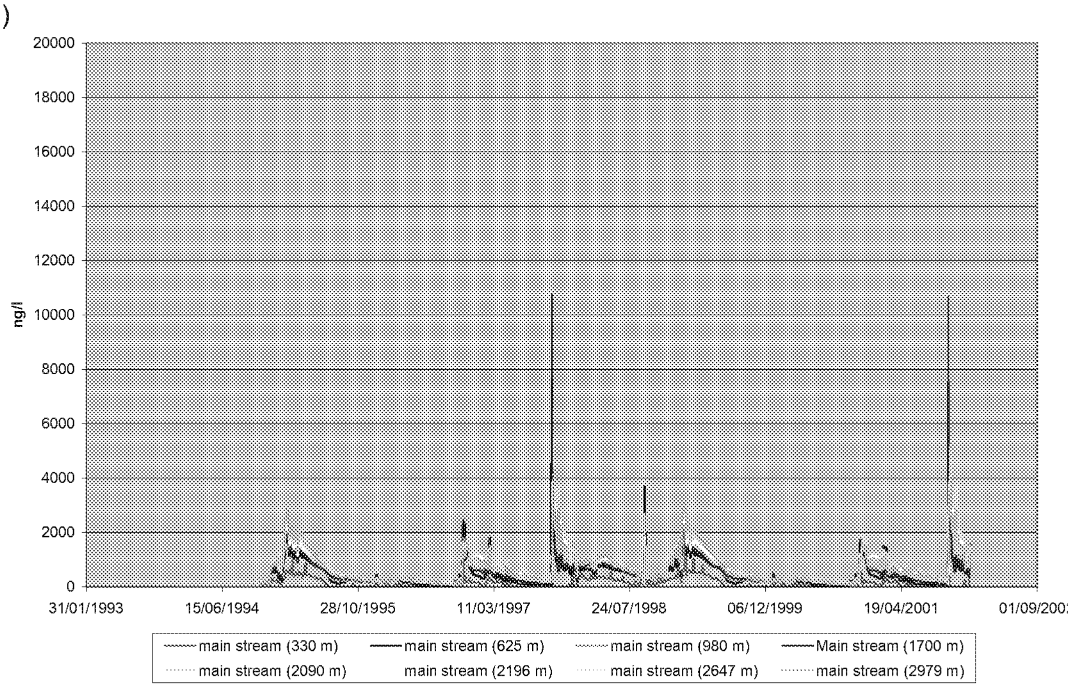
Name of stream, distance from top	Concentration ng/l	Date of max. conc.	Comment
Tributary 1 150 m	2189	28.12.2001	
Tributary 2 165 m	781	15.02.1999	
Tributary 3 200m	4453	18.11.2000	
Tributary 4 155 m	3131	03.02.1999	
Tributary 5 125 m	163559	09.10.2001	spray drift
Main stream 125 m	2779	15.02.1999	
Main stream 330 m	1331	15.02.1999	
Main stream 625 m	10636	09.10.2001	spray drift
Main stream 980 m	4518	16.10.2001	
Main stream 1700 m	2941	16.10.2001	
Main stream 2090 m	3899	17.10.2001	
Main stream 2196 m	4698	17.10.2001	
Main stream 2647 m	5287	17.10.2001	
Main stream 2979 m	4281	17.10.2001	

Figure A2.5. Timeseries of concentrations for selected points in the sandy clay stream setup. a) tributaries and the top end of the main stream, b) points along the main stream. Note that the concentrations in the tributaries are higher than further down in the stream system.

a)



b)

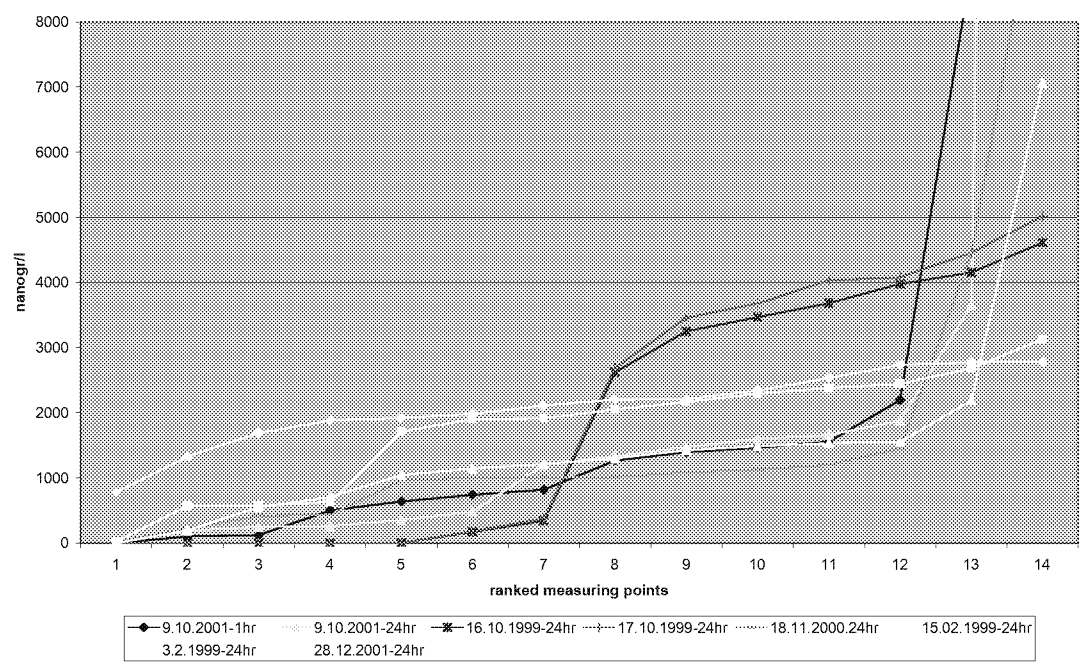


It should be noted that one tributary provides very large simulated PEC's during a drift event in the last simulation year. These occurrences are analysed further below.

Table A2.6. Maximum concentrations for each of the stream points shown in Figure A2.5 and the date in the evaluation period (1998-2001) that it occurs.

Name of stream, distance from top	Concentration ng/l	Date of max. conc.	Comment
Tributary 1 150 m	2189	28.12.2001	
Tributary 2 165 m	781	15.02.1999	
Tributary 3 200m	4453	18.11.2000	
Tributary 4 155 m	3131	03.02.1999	
Tributary 5 125 m	163559	09.10.2001	spray drift
Main stream 125 m	2779	15.02.1999	
Main stream 330 m	1331	15.02.1999	
Main stream 625 m	10636	09.10.2001	spray drift
Main stream 980 m	4518	16.10.2001	
Main stream 1700 m	2941	16.10.2001	
Main stream 2090 m	3899	17.10.2001	
Main stream 2196 m	4698	17.10.2001	
Main stream 2647 m	5287	17.10.2001	
Main stream 2979 m	4281	17.10.2001	

Figure A2.6. Ranked concentrations for the stream points shown in Figure A2.5 and Table A2.5 for the dates where the maximum concentrations occur. The very high concentrations are found in only a few points in the catchment at each event, and in this case they are due to spray drift into almost dry tributaries. On 16-17.10 1999, almost half the catchment shows concentrations higher than 3 ∝g/l.



A2.4 Interpretation of risk potential based upon Step 4 exposure assessment

At the conclusion of the Step 3 risk assessment, the remaining concern was associated with potential impact of exposure to algae. The critical endpoint for this assessment was an acute (72 h) EC50 of 81 ∝g/l. By applying an assessment factor of 10, the resulting PNEC value would then by 8.1 ∝g/l. This is an effective target exposure threshold that should not, ideally, be exceeded in the risk assessment. When this threshold is compared against the results of this more complex modelling it can be seen that in almost all cases exposure would not result in any concerns. However, in two specific examples (Tributary 5 125 m and Main stream 625 m), this threshold is exceeded – and in one case significantly exceeded. TER values based upon the maximum exposure values summarised in Table A2.5 are provided below, for illustrative purposes.

However, as described previously the maximum PEC value in one case (Tributary 5 125 m) was associated with a drift event into an almost dry system. Further, more detailed interpretation of the hydrology simulations revealed that at this point in the simulations the water body at this location had a depth of no more than 1 cm. The tributary was dry until the day before the event. Therefore, it is suggested that apparent risk needs to be placed into a context of ecological significance. It is apparent that at this point in the catchment the water body is periodically dry and physical stressors are likely to greatly exceed those associated with the chemical of concern. The PNEC endpoint was also exceeded at another point (Main stream, location: 625 m from the top of the system). This was associated with the same drift event. Also in this case, the stretch was dry until the day before the event, but the water depth ranged between 10 and 15 cm during the morning of spraying.

Table A2.7. Maximum concentrations for each of the stream points shown in Figure A2.4 and associated algal TER values

Name of stream, distance from top	Concentration ng/l	Algal TER	Comment
Tributary 1 150 m	2189	37.00	
Tributary 2 165 m	781	103.71	
Tributary 3 200m	4453	18.19	
Tributary 4 155 m	3131	25.87	
Tributary 5 125 m	163559	0.50	spray drift
Main stream 125 m	2779	29.15	
Main stream 330 m	1331	60.86	
Main stream 625 m	10636	7.62	spray drift
Main stream 980 m	4518	17.93	
Main stream 1700 m	2941	27.54	
Main stream 2090 m	3899	20.77	
Main stream 2196 m	4698	17.24	
Main stream 2647 m	5287	15.32	
Main stream 2979 m	4281	18.92	

In Tributary 5, the value of 8.1 µg/l is exceeded in one event over the four years, during a total of five hours. In Main stream 625, the value of 8.1 µg/l is exceeded in one event over the four years, for less than 1 hour. In the last case, the 24-hour average is 3.7 µg/l and thus below the PNEC-value. The dry year of the simulation period corresponds to 1997, which was the second-driest year of the period 1990-2000, meaning that the return period in reality is less than one in four years.

The example thus illustrates that if whole catchments are modelled, it becomes necessary to consider the relevance of concentrations calculated in different parts of the stream system. When placed into a probabilistic context, it is clear that concerns are potentially limited to a very short time period. Further evidence from algal studies may allow investigation of recovery potential following these very short exposure events. This would provide further evidence that impacts to algae are likely to be much reduced relative to Step 3 FOCUS modelling.

The catchment modelling study is considered to have provided a high quality basis for risk assessment that has enabled risks to algae to be placed in a clearer context. A number of points are worthy of consideration:

- Simulations are based upon an actual usage environment where agricultural practices have been surveyed;

- Simulations have been established upon highly conservative assumptions regarding usage (e.g. 100% of agricultural land within the catchment is treated simultaneously);
- The catchment in question has been intensively characterised;
- Hydrological simulations have been the subject of validation exercises;
- Simulations have been characterised in terms of scale of exceedance of a critical threshold, as well as the hydrological context and frequency and duration of these exceedances.

References

Abbott, M.B., Bathurst, J.C., Cunge, J.A., O'Connell, P.E. and Rasmussen, J. (1986): An introduction to the European Hydrological System - Systéme Hydrologique Européen SHE 2: Structure of a physically based distributed modelling system. Journal of Hydrology, 87: 61-77.

Henriksen, H.J and Sonnenborg, A. (Eds) (2003): Ferskvandets kredsløb.NOVA 2003 Temarapport

Refsgaard, J.C. and Storm, B. (1995): MIKE SHE. In Singh, V.P. (Ed.). Computer Models of Watershed Hydrology, Water Resources Publication, 809-846.)

Styczen, M., Petersen, S., Christensen, M., Jessen, O.Z., Rasmussen, D., Andersen, M.B. and Sørensen, P.B. (2004): Calibration of models describing pesticide fate and transport in Lillebæk and Odder Bæk Catchment. - Ministry of Environment, Danish Environmental Protection Agency, Pesticides Research No. 62.

Styczen, M., Petersen, S. Sørensen, P.B., Thomsen, M and Patrik, F. (2004): Scenarios and model describing fate and transport of pesticides in surface water for Danish conditions. - Ministry of Environment, Danish Environmental Protection Agency, Pesticides Research No. 63.

Styczen, M., Petersen, S., Olsen, N.K. and Andersen, M.B. (2004): Technical documentation of PestSurf, a model describing fate and transport of pesticides in surface water for Danish Conditions. - Ministry of Environment, Danish Environmental Protection Agency, Pesticides Research No. 64.

A3 ILLUSTRATION OF A POSSIBLE APPROACH TO REFINING ESTIMATES OF EXPOSURE VIA DRAINFLOW – BRIMSTONE

The FOCUS Landscape and Mitigation working group addressed possible refinements to risk assessment to support listing on Annex I and for national registration procedures. This example is for a refinement specific to a particular usage scenario; it is thus most applicable at the level of an individual Member State, but the broad approach is generic. The example is intended to be illustrative; it does not replicate a regulatory submission (e.g. the level of detail and justification of decisions are both less than would be required) and is not intended to be prescriptive. A detailed opinion of the illustration is available from PPR (2006), including information on additional requirements and/or considerations where the broad approach is used for a regulatory submission.

Use Profile

Product 'CONTROL 500' is based on the active substance herbalin. The product is used pre- and early post-emergence in winter cereals to control annual grasses including blackgrass. Usage rate is proposed as 0.5 kg a.s./ha.

Problem Summary

Exposure assessment modelling within the FOCUS Surface Water Framework at Step 3 suggests that risk to fish, *Daphnia* and algae is acceptable within all scenarios.

However, Step 3 modelling highlights potential concern surrounding risks to aquatic plants associated with a product in scenario D2 (ditch scenario only).

The D2 scenario is mainly correlated with parts of England and with a smaller proportion of land in France. As the UK is a key market for CONTROL 500, additional work is undertaken at Step 4 to address the potential risk in the D2 scenario.

Strategy

The strategy focuses upon assessing exposure under the range of conditions relevant to winter cereal cultivation in the UK. Concentrations of herbalin in a standardised ditch are calculated following use on UK drained soils with a range of properties and in regions with different climatic conditions. The Denchworth soil from the D2 scenario is included as one of the soils simulated, but an analysis is undertaken to select a more representative example of this series.

If risks to aquatic macrophytes from the refined assessment are considered unacceptable, the analysis is designed to support discussions on the possibility of mitigation based on restricting use on vulnerable soils.

A3.1 Step 3 FOCUS surface water calculations

Use on winter cereals dictates that nine of the ten FOCUS surface water scenarios are simulated. The properties of herbalin are summarised below:

Proposed use	Pre- and early post-emergence to winter cereals at 500 g a.s. ha^{-1}
Application window	Planting to GS11
Molar mass	400
Saturated vapour pressure	1×10^{-6} Pa
Solubility	500 mg L^{-1} at pH 7
Sorption Koc (median)	75 L kg^{-1} selected
Half-life in soil (median)	25 days (field value)
Half-life in water	10 days
Half-life in sediment	30 days
Critical ecotoxicity value	0.30 mg L^{-1} (7-day EC50 for *Lemna gibba*)

Maximum PECsw values at FOCUS Step 3 range from 0.3 to 43.5 µg L^{-1} and TER values for *Lemna* range from 6.9 to 968 (Table A3.1). The assessment indicates that risk to aquatic macrophytes is acceptable in all scenarios apart from the ditch in D2. The D2 scenario is a 99.3 percentile worst case for all drained agricultural land (FOCUS, 2002). As extensive safe uses have been demonstrated, risk of herbalin to aquatic macrophytes is acceptable with respect to listing on Annex 1. The D2 scenario is mainly correlated with parts of England and with a smaller proportion of land in France. As the UK is a key market for herbalin, additional work is undertaken at Step 4 to address the potential risk in the D2 scenario.

Table A3.1. Step 3 PEC_{SW} and TER values based on a 7-day EC50 for *Lemna gibba* of 0.3 mg L^{-1}.

Scenario	Water body	Maximum PEC_{SW} (µg L^{-1})	TER
D1	Ditch	12.913	23.2
D1	Stream	11.472	26.2
D2	Ditch	43.525	6.9
D2	Stream	27.240	11.0
D3	Ditch	3.159	95.0
D4	Pond	0.555	540.5
D4	Stream	2.741	109.4
D5	Pond	1.506	199.2
D5	Stream	2.957	101.5
D6	Ditch	17.463	17.2
R1	Pond	0.310	967.7
R1	Stream	2.854	105.1
R3	Stream	29.529	10.2
R4	Stream	2.096	143.1

A3.2 Methodology for Step 4 assessment

A3.2.1 Potential options

There are several options for refinement of the risk assessment, including:

[1] The relevance of the D2 scenario might be considered with respect to the proposed area of use. Areas correlated with the D2 scenario are used for cultivation of winter cereals in the UK, so this is not pursued here.

[2] The Denchworth soil used to select parameters for the D2 scenario is a relatively extreme example of this soil type (Hollis, 2003). It would be possible to refine soil parameters for the D2 soil to describe a more representative Denchworth soil.

[3] The effects endpoint could be refined by, for example: (i) testing further macrophyte species with a range of growth habits (information on the flora and fauna of water bodies within a small area around the Brimstone site are available from Williams et al., 2004); (ii) considering the potential for recovery from effects; (iii) considering the effects of pulsed exposures of pesticide. Peaks in pesticide concentration in the D2

ditch are generally short-lived and there are significant possibilities to refine the assessment by considering the implications of the temporal variation in exposure.

[4] Options to mitigate aquatic risk arising from pesticide transport in drainflow are limited, but restriction of use on the most vulnerable soils is a possibility where the legal framework allows. Refined exposure assessment would need to demonstrate how exposure varies with soil type and/or climate.

The approach adopted below is confined to the exposure part of the risk assessment and combines options [2] and [4] above. It is broadly based on work recently reported by Brown et al. (2004). Concentrations of herbalin in a standardised ditch are calculated for use on drained soils in the UK with a range of properties and in regions with different climatic conditions. The Denchworth soil from the D2 scenario is included as one of the soils simulated, but an analysis is undertaken to select a more representative example of this soil type. **The aim of the Step 4 modelling is to assess exposure under the range of conditions relevant to winter cereal cultivation in the UK; if risks to aquatic macrophytes from the refined assessment are considered unacceptable, the analysis is designed to support discussions on the possibility of mitigation based on restricting use on vulnerable soils.**

A3.2.2 Details of Step 4 Methodology

The area of winter cereal-growing land in England and Wales (*ca.* 1.7 x 10^6 ha) was divided into environmental scenarios comprising discrete classes of soil type and climate. The analysis was undertaken using the SEISMIC database (Hallett et al., 1995), a modelling support tool which allows climate, cropping and soil data to be overlaid and then provides basic environmental properties useful for deriving model input parameters. First, areas of winter cereal cultivation were overlaid onto those soils likely to be drained under arable cultivation to generate an estimate that 54% of the area cultivated with winter cereals in England and Wales is likely to be artificially drained. The soil series making up the drained winter cereal area were then divided into six broad classes (Table A3.2) based upon vulnerability for leaching via drainflow. The division was made subjectively based on the prevalence of rapid movement to drains via macropore flow (determined by clay content and structure). Drained soils with peaty topsoils were considered to have no vulnerability for leaching via drainflow because sorption of pesticides will be strong. Hence, only five of the six soil classes were considered within the modelling. A representative soil series was selected as lying at the vulnerable end of each of the five remaining classes (Table A3.2). For each representative series, profile information was extracted from SEISMIC (Table A3.3) and used to parameterise the MACRO model. Details of the parameterisation approach are given in Brown et al. (2004); the adequacy of the derived parameters has been evaluated using results from field experiments for the Hanslope soil (Brown et al., 2004) and the Denchworth soil (Beulke et al., 2001).

Whereas each soil series was chosen at the vulnerable end of the class which it represents, the properties chosen were the average of all available measurements for that series in England and Wales. A recent analysis compared the Denchworth soil used as the basis for the D2 scenario with measurements for *ca*. 120 Denchworth series soils under arable or ley grass cultivation in England and Wales (Hollis, 2003). It was shown that the D2 soil represents a 75th percentile worst-case for preferential flow (clay content) within the series and a 35th percentile worst case for pesticide sorption (organic carbon content). The Denchworth series used in Step 4 modelling (2.9% OC and 43% clay in the topsoil) thus differs from that parameterised in the D2 scenario (3.3% OC and 54% clay in the topsoil).

Table A3.2. Division of the winter cereal-growing land in England and Wales into soil vulnerability classes

<table>
<tr><th>Representative soil series</th><th colspan="2">Description of soil class</th><th>Proportion of winter cereal-growing land (%)</th></tr>
<tr><td>Denchworth</td><td colspan="2">Clayey soils with a strong inhibition to downwards movement of water which have a soft impermeable layer within 100 cm of the soil surface and a gleyed layer within 70 cm depth</td><td>7.0</td></tr>
<tr><td>Hanslope</td><td>Soils with clayey upper layers</td><td rowspan="3">Soils with either (a) significant inhibition of downwards movement of water which have a slowly permeable and a gleyed layer within 100 cm of the soil surface, or (b) prolonged seasonal saturation and a gleyed layer within 40 cm of the soil surface as a result of shallow groundwater</td><td>15.5</td></tr>
<tr><td>Brockhurst</td><td>Soils with clayey lower layers and lighter-textured upper layers</td><td>15.1</td></tr>
<tr><td>Clifton</td><td>Medium loamy and silty soils</td><td>9.2</td></tr>
<tr><td>Quorndon</td><td colspan="2">Relatively permeable soils with a gleyed layer within 40 cm of the soil surface as a result of shallow groundwater</td><td>3.8</td></tr>
<tr><td>(None assigned)</td><td colspan="2">Soils with humose or peaty layers</td><td>3.5</td></tr>
</table>

Table A3.3. Properties of the five representative soil series selected for scenario-based modelling (values for ASCALE are derived during parameterisation)

	Depth interval (cm)	Organic carbon (%)	Sand (%)	Silt (%)	Clay (%)	Bulk density (g cm^{-3})	pH (1:2.5 in H_2O)	ASCALE (mm)
Denchworth series								
Horizon 1	0-20	2.9	17	40	43	1.17	6.3	20
Horizon 2	20-50	1.2	6	30	64	1.26	6.9	20
Horizon 3	50-70	0.8	5	31	64	1.31	7.0	50
Horizon 4	70-100	0.4	6	36	58	1.40	7.4	50
Hanslope series								
Horizon 1	0-25	2.9	30	32	38	1.18	7.7	20
Horizon 2	25-50	0.9	22	36	43	1.38	8.2	20
Horizon 3	50-65	0.5	20	33	47	1.45	8.3	20
Horizon 4	65-100	0.4	14	45	41	1.44	8.3	50
Brockhurst series								
Horizon 1	0-25	2.3	32	42	26	1.26	6.4	10
Horizon 2	25-45	0.6	30	44	26	1.49	6.4	20
Horizon 3	45-70	0.3	14	40	46	1.48	6.7	150
Horizon 4	70-100	0.2	7	48	45	1.51	7.5	50
Clifton series								
Horizon 1	0-25	3.1	50	30	20	1.20	5.9	10
Horizon 2	25-40	0.5	52	31	17	1.52	6.2	10
Horizon 3	40-75	0.4	38	32	30	1.55	6.8	100
Horizon 4	77-100	0.2	36	32	32	1.64	7.2	100
Quorndon series								
Horizon 1	0-30	2.7	60	25	15	1.25	7.1	10
Horizon 2	30-80	0.6	68	21	11	1.41	6.3	25
Horizon 3	80-120	0.3	73	18	9	1.43	6.3	10

Areas of winter cereal cultivation in England and Wales were divided into four approximately equal climatic classes designated 'dry' (<625 mm precipitation per annum), 'medium' (625-750 mm p.a.), 'wet' (750-850 mm p.a.) and 'very wet' (>850 mm p.a.). Four weather datasets were then selected from the SEISMIC database as representative of the four climatic classes. Average annual rainfall for the four datasets was 588, 713, 815 and 1115 mm (Table A3.4).

Table A3.4. Annual rainfall statistics (30 years) for the weather stations selected to represent the three climate scenarios (all values in mm)

Year	Cambridge (dry scenario)	Mylnefield (medium scenario)	Keele (wet scenario)	Rosewarne (very wet scenario)
30-year average	588	713	815	1115
Standard deviation	80	86	99	119
Minimum	447	526	614	858
Maximum	784	872	977	1361

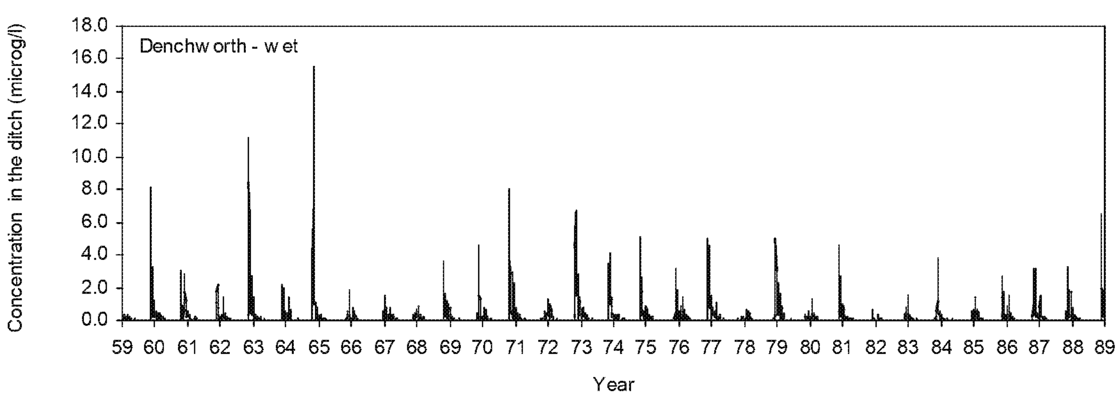
The model was run for the 20 scenarios resulting from the combination of five soil and four climate classes and assuming annual applications of the test compound in the autumn of each of 30 years. The target application date varied between 5 and 25 October according to the scenario. Application was delayed to the first subsequent dry day where rainfall exceeded 2 mm on the target application date or 7 mm on either of the next two days. Rainfall of 7 mm was considered an amount that could be reasonably forecast as heavy rainfall and where a farmer might delay application to protect efficacy. A simple approximation of dilution within a small receiving water body was considered on the basis of drainflow from a 1-ha field entering a ditch 100 m long, 1 m wide and with a water depth of 30 cm. It was assumed that the residence time of water in the ditch was one day, so that the daily input of drainflow and pesticide always entered the same volume of uncontaminated water.

A3.3 Results of Step 4 Assessment

The annual drainage predicted by MACRO varied greatly between climatic classes and to a much lesser extent between soil types. Annual average drainage (and range) for the Denchworth soil series was 105 mm (20-244 mm) for the dry climate, 236 mm (88-353 mm) for the medium climate, 318 mm (149-466 mm) for the wet climate and 674 mm (429-902 mm) for the very wet climate. The D2 scenario at Step 3 lies within the medium climate class and the model prediction of 236 mm drainage on average agrees with the classification by FOCUS (2002) that the D2 scenario has average recharge of 200-300 mm (categorised by FOCUS as a worst-case for recharge when considering all drained land in Europe).

Output of the Step 4 exposure assessment was the daily concentration of herbalin in the standardised ditch. Concentrations varied in time in a pattern characteristic of transport to drains via preferential flow. Short-lived peaks in concentration were observed during major flow events, with concentrations being largest when flow occurred soon after application (Figure A3.1).

Figure A3.1. Example of daily concentrations of herbalin predicted in the receiving ditch (example shown is for Denchworth soil coupled with a 'wet' climate)



The maximum daily concentration of herbalin in the ditch during each year of a simulation was taken as the value for use in refined risk assessment. This matches the approach taken at FOCUS Step 3 where the largest daily concentration is taken for acute risk assessment. However, FOCUS Step 3 considers a more limited timescale (a single year), so the long-term assessment undertaken at Step 4 provides a broader temporal context within which to interpret results. **As discussed above, concentrations in the ditch vary greatly with time and a more complete analysis could consider all daily values to describe the duration as well as magnitude of peaks in exposure, time between exposure events etc.**

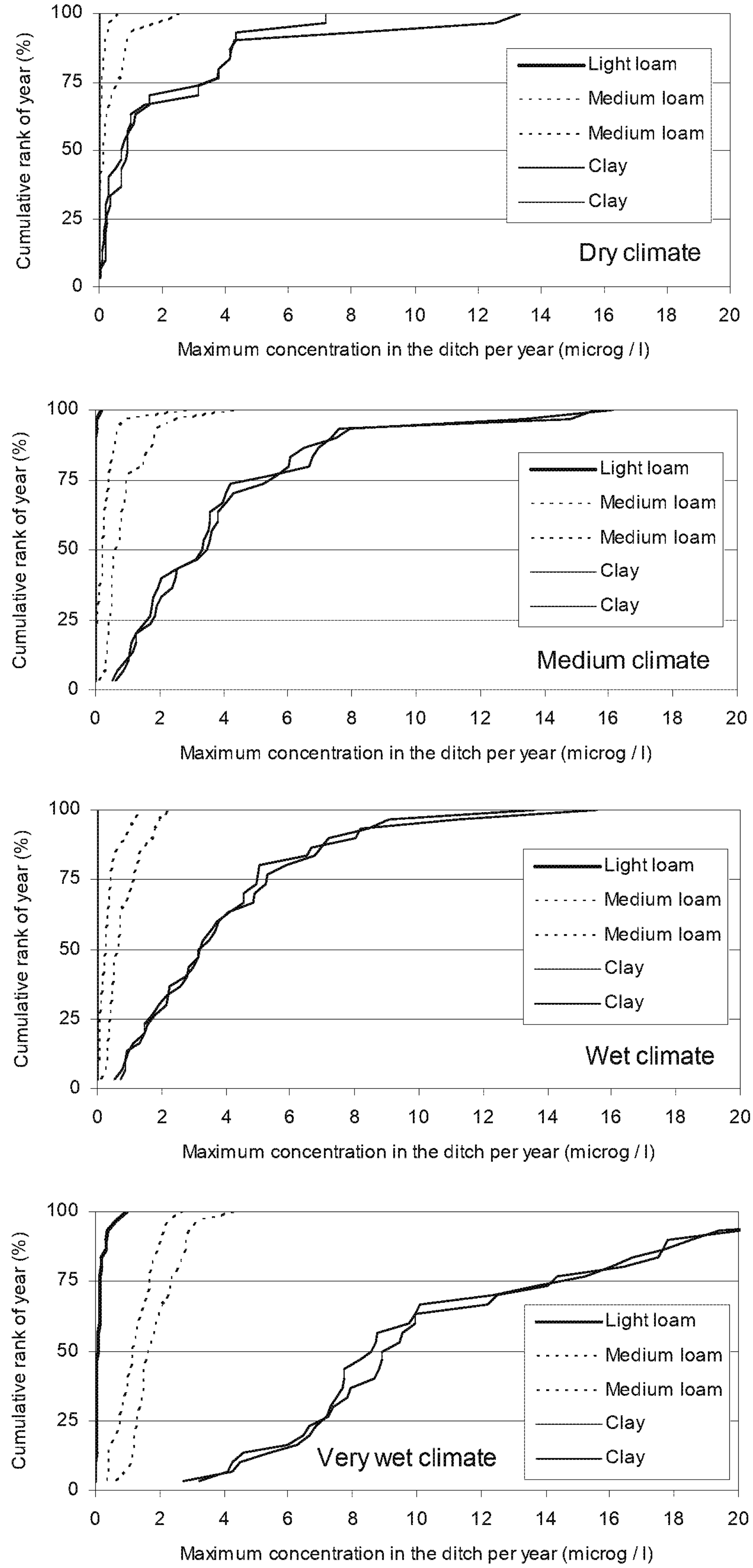
An initial check of the method of calculating dilution within the ditch was undertaken. The daily concentration output from MACRO that gave rise to the largest PECsw value for the D2 ditch at Step 3 (43.53 $\mu g\ L^{-1}$) was 110.48 $\mu g\ L^{-1}$. This equates to a dilution factor for raw drainflow within the ditch of 2.5. In comparison, the average dilution of peak concentration in drainflow was a factor of 1.8 in Step 4 calculations. Although the calculation procedure is simplistic, it gives a more conservative estimate. **A more complete analysis could use output from long-term simulations with MACRO as input to FOCUS-TOXSWA as at Step 3.**

For each combination of soil type and climate (5 x 4 = 20), there were 30 years in each simulation and the largest daily concentration in the ditch in each year was taken as output and ranked into a cumulative distribution. Results are summarised in Table A3.5 and Figure A3.2. **A more complete analysis could consider the distribution of all daily concentrations in the ditch for each of the 20 scenarios (rather than just the annual maximum in each year).**

Table A3.5. Selected values from cumulative distributions of the maximum annual concentration (µg/L) of the pesticide in the ditch (30 values per distribution)

	Light loam (Quorndon)	Medium loam (Clifton)	Medium loam (Brockhurst)	Clay (Hanslope)	Clay (Denchworth)
Dry climate					
50th percentile	0.00	0.00	0.15	0.88	0.71
80th percentile	0.00	0.13	0.75	3.77	3.77
90th percentile	0.00	0.20	0.91	4.33	4.28
100th percentile	0.00	0.67	2.64	7.18	13.38
Medium climate					
50th percentile	0.00	0.24	0.65	3.49	3.36
80th percentile	0.00	0.49	1.52	6.02	6.66
90th percentile	0.02	0.63	1.85	7.50	7.34
100th percentile	0.19	3.18	4.56	16.11	15.57
Wet climate					
50th percentile	0.00	0.27	0.66	3.14	3.18
80th percentile	0.00	0.50	1.29	5.90	5.07
90th percentile	0.00	0.91	1.79	7.22	8.05
100th percentile	0.00	1.31	2.30	13.64	15.52
Very wet climate					
50th percentile	0.08	1.20	1.68	8.56	8.93
80th percentile	0.18	1.77	2.66	16.44	16.04
90th percentile	0.35	2.05	2.86	17.79	18.52
100th percentile	1.00	2.75	4.53	43.07	41.82

Figure A3.2. Cumulative ranked distributions for concentrations of herbalin in the receiving ditch. Each curve comprises the maximum daily concentration in each of the 30 years simulated for that combination of soil and climate. The curve for the light loam lies very close to the y-axis.



A3.4 Risk assessment based on Step 4 results

The modelling was based on environmental scenarios specific to a particular area of use. Within this framework, TER values are predicted to exceed 10 throughout the 30-year simulations for all soil types in the dry, medium and wet climates. TER values are predicted to be less than 10 for at least one day in only one of the 30 years simulated for the two clay soils in the very wet climate (TER 7.0-7.2). Data on the proportion of winter cereals grown on different soil types and in different climates show that cultivation on clay soils in the very wet climate is extremely restricted (<1% of the total; Table A3.6).

TableA3.6. Proportion of the total winter cereal land in England and Wales accounted for by each scenario

Soil type	Extent of soil within each climatic scenario (%)				Total extent
	Dry	Medium	Wet	Very wet	(%)
Undrained	-	-	-	-	45.9
Peaty soils	-	-	-	-	3.5
Denchworth	2.7	3.0	0.8	0.5	7.0
Hanslope	9.0	5.6	0.5	0.4	15.5
Brockhurst	4.8	7.6	1.8	0.9	15.1
Clifton	1.5	5.2	1.6	0.9	9.2
Quorndon	2.4	0.9	0.3	0.2	3.8
Total	20.4	22.3	4.9	2.9	100.0

The absolute maximum concentrations predicted at Step 4 for the clay soils in the very wet climate are very similar to that predicted for the D2-ditch scenario at Step 3. The parameterisation of the Denchworth clay scenario using a representative profile for this series has a significant impact on exposure concentrations relative to the 'Brimstone' soil parameterised in the D2 scenario.

Comparison of results for the various scenarios shows a strong influence of soil type and climate on predicted exposure. Concentrations in the ditch following treatment of the light loam (15% topsoil clay) are negligible under all but the wettest conditions. Exposure predicted for the two medium loams (20-26% topsoil clay) is roughly an order of magnitude smaller than that for the two clay soils (38-43% topsoil clay). In general, exposure concentrations are largest for the very wet climate and smallest for the dry climate with those for the medium and wet climates being between these two extremes and broadly similar to each other.

In the current instance, the assessment suggests acceptable risk to aquatic macrophytes under normal usage conditions, with only a very infrequent exceedence of the TER trigger value for use on heavy clay soils under very wet conditions. If the outcome following Step 4 refinement had been some residual risk, results show the potential to mitigate risk by restricting use of the compound on the most vulnerable soil types.

References

Beulke, S., Brown, C.D., Dubus, I.G. & Harris, G.L. (2001). Evaluation of uncalibrated preferential flow models against data for isoproturon movement to drains through a heavy clay soil. *Pesticide Science*, 57:537-547.

Brown CD, Dubus IG, Fogg P, Spirlet M, Reding M-A, Gustin C (2004). Exposure to sulfosulfuron in agricultural drainage ditches. *Pest Management Science* 60:765-776.

FOCUS (2002). FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC. Report SANCO/4802/2001-rev.1.

Hallett SH, Thanigasalam P and Hollis JM (1995). SEISMIC: a desktop information system for assessing the fate and behaviour of pesticides in the environment. *Comput Electron Agr* 13:227-242.

Hollis JM (2003). Statistical analysis of national soil inventory data for England and Wales to identify the 'worst-case' nature of the 'Brimstone' FOCUSsw D2 soil. National Soil Resource Institute report SR9088S, Silsoe, Bedford, UK, p13.

Williams P, Whitfield M, Biggs J, Bray S, Fox G, Nicolet P, Sear D (2004). Comparative biodiversity of rivers, streams, ditches and ponds in an agricultural landscape in Southern England. *Biological Conservation* 115:329-341.

A4 ILLUSTRATION OF A POSSIBLE APPROACH TO REFINING EXPOSURE VIA SPRAY DRIFT – VALENCIA

The FOCUS Landscape and Mitigation working group addressed possible refinements to risk assessment to support listing on Annex I and for national registration procedures. This example is for a refinement specific to a particular usage scenario, but the broad approach is generic. The example is intended to be illustrative; it does not replicate a regulatory submission (e.g. the level of detail and justification of decisions are both less than would be required) and is not intended to be prescriptive. A detailed opinion of the illustration is available from PPR (2006), including information on additional requirements and/or considerations where the broad approach is used for a regulatory submission.

Use Profile

The product of concern is an emulsifiable concentrate (EC) formulation of a novel insecticide for use in citrus. The product is used for the pre-emergence control of lepidopteran, coleopteran and dipteran pests.

Problem Summary

Step 1 and 2 calculations indicated potential concerns associated with acute risk to fish and aquatic invertebrates.

More sophisticated exposure assessment modelling employing the FOCUS Surface Water Scenarios at Step 3 suggests that acute risks remain for fish and aquatic invertebrates, but the scale of concern has been reduced.

Further investigation of the acute exposure profile is warranted at Step 4 for R4 and D6 scenarios.

Due to the exposure profile at Step 3 and the properties of the compound, it was concluded that the most appropriate expenditure of effort at Step 4 would be a consideration of more realistic spray drift loadings into the edge of field water bodies within a known landscape.

An analysis of a suitably representative landscape may provide sufficient evidence of naturally existing mitigation in the form of existing margins between crop and water bodies.

Considering the nature of citrus culture, due consideration should also be given to the type of water bodies that would be exposed and the organisms that they would contain.

Strategy

The strategy focuses on use of landscape level data to quantify the extent and magnitude of naturally existing mitigation in relation to spray drift. The impact of directional variability on spray drift should also be considered (i.e., the wind is not always blowing towards the water body).

A site selection process should be undertaken to identify an appropriate area for landscape study, based primarily on the presence of citrus orchards.

Once a study area is selected, the best available spatial data sets for land cover and surface water should be obtained, and made available to process in a Geographic Information System (GIS). Relevant information regarding surface water should be maintained in the processing (for example, water body widths, permanent *vs.* intermittent water bodies, and the separation of natural streams and artificial canals).

PECsw values arising from drift should be calculated using the standard methods and values used in the FOCUS Drift Calculator.

Other assumptions about drift entry and surface water PECs should remain unchanged from Step 3 (e.g. water body depth, mixing, simultaneous applications, etc), with refined PEC's being determined solely by citrus density, direction and proximity to surface water.

For ease of interpretation and refinement of Step 3 output, results of landscape-level PEC's will be presented as the "percent of maximum PEC" (where maximum PEC is calculated according to the FOCUS Drift Calculator), rather than PEC's specific to application rate.

Given the potential differences in aquatic habitats in Mediterranean agricultural areas (natural streams *vs.* concrete canals), elements of ecological information should be incorporated into the evaluation of the exposure information if possible.

A4.1 Profile of Active Substance and FOCUS SW Modelling

A4.1.1 Profile of the Active Substance

The product of concern is an EC formulation of a novel insecticide for use in citrus. The product is used in the pre-emergence control of lepidopteran, coleopteran and dipteran pests. Usage rate is 42 g a.s./ha. The following ecotoxicology profile is used in the risk assessment:

Fish LC_{50} (96 h static mortality):	133 ∝g/l
Aquatic invertebrate EC_{50} (48 h static immobilisation):	97 ∝g/l
Algae EC_{50} (72 h growth):	64 ∝g/l
Fish NOEC (21 d):	17 ∝g/l
Aquatic invertebrate NOEC (21 d):	3 ∝g/l

A4.1.2 Simulation Results – FOCUS Step 1 and 2

Maximum PEC values for the active substance at Step 1 and 2 were 4.32 and 2.20 ∝g/l, respectively. These result in the following acute TER profiles:

	Step 1 TER	Step 2 TER
Fish LC_{50} (96 h static mortality):	30	60
Aquatic invertebrate EC_{50} (48 h static immobilisation):	22	43
Algae EC_{50} (72 h growth):	14	29

Chronic endpoints were also compared with maximum PEC values as summarised below.

	Step 1 TER	Step 2 TER
Fish NOEC (21 d):	3.9	7.7
Aquatic invertebrate NOEC (21 d):	0.7	1.4

A review of the toxicity profiles (time to effect) and mode of action suggests that the use of time-weighted average PEC's for chronic assessments is justified. Comparisons with 21d time-weighted average PEC's at Step 1 and 2 of 2.31 and 0.17 ∝g/l allow a refined chronic risk assessment for fish and aquatic invertebrates:

	Step 1 TER	Step 2 TER
Fish NOEC (21 d):	7.36	100
Aquatic invertebrate NOEC (21 d):	1.36	18

Accordingly, after a Step 1 and 2 exposure assessment, acute risks to fish and aquatic invertebrates cannot be discounted and, as a consequence further assessments at Step 3 are necessary. At Step 2, chronic TER values for fish, aquatic invertebrates and algae all exceed 10, indicating low potential for risk.

A4.1.3 Simulation Results – FOCUS Step 3

Citrus is associated with two FOCUS surface water scenarios (D6 and R4). The results of simulations considering drift and run-off or drainage loadings into each system are summarised below:

	R4 Stream	D6 Ditch
Maximum PEC(∝g/l):	1.177	1.543
21 d TWA PEC (∝g/l):	0.015	0.073

These maximum PEC values result in the following TER profiles:

	R4 Stream TER	D6 Stream TER
Fish LC_{50} (96 h static mortality):	111	85
Aquatic invertebrate EC_{50} (48 h static immobilisation):	82	62
Algae EC_{50} (72 h growth):	54	41
Fish NOEC (21 d):	1133	233
Aquatic invertebrate NOEC (21 d):	200	41

Accordingly, after a Step 3 exposure assessment, acute risks remain for fish and aquatic invertebrates, but the extent of concern has been reduced. Further investigation of the acute exposure profile is warranted at Step 4. As before, chronic TER values for fish, aquatic invertebrates and algae all exceed 10, implying low potential for risk.

A4.2 Step 4 Strategy

Unacceptable exposure profiles were identified in both the R4 and D6 scenarios. Interpretation of the results of simulations at Step 3 shows that entry via spray drift is the more important route of exposure.

Scenario	Drift	Run-off / Drainage
R4	0.049 g	0.027 g
D6	0.047 g	<0.001 g

The runoff calculation includes a conservative assumption on the slope of the orchards. Whereas newer orchards tend to be positioned on terraced hillsides, many of the older orchards occupy flatter land.

It was concluded that the most appropriate focus of efforts at Step 4 would be a consideration of more realistic spray drift loadings into the edge of field water bodies within a known usage landscape. Mitigating influences on drift include choice of equipment, tractor and wind speed and distance to the water body. It was decided that an analysis of the landscape may provide sufficient evidence of naturally existing mitigation in the form of existing margins between crop and water bodies.

A4.3 Landscape characterisation

A4.3.1 Site Selection

The process of selecting an appropriate area for examination is crucial to the understanding and interpretation of the results of that examination. This "site selection" process should be carefully considered prior to the initiation of any landscape level analysis. Site selection is a step-wise process starting from a trans-national scale (EU), with periodic refinements in scale and data until a specific area has been identified for landscape-level analysis. The example for citrus starts with a general view of citrus (tree fruit) production in the southern EU, then moves to a national level (for which data sets with consistent quality and content are usually available), to a regional level and finally to the local level. An EU-wide examination of hydrologic density could not be performed due to the lack of pan-European databases at the time of analysis. However, when a pan-European hydrology data set becomes available, it should be considered for use in the site selection process. Lacking pan-European data for this example, the potential study areas were narrowed down by area cultivated to the Member State level. A hydrologic density metric could also be computed at the Member State level to further refine site selection for drift exposure within the Member State.

EU-Level

The Food and Agriculture Organisation of the United Nations (FAO) statistical database on agricultural production (FAOStat) was used to examine citrus production across the entire EU. These results show that Spain consistently produces the greatest amount of citrus of all EU countries (slightly more than 50% of total EU production). Use of the product in Spain could therefore be considered a major use relevant to decision-making under Annex I of Directive 91/414/EC. While agricultural and environmental factors do not necessarily follow Member State boundaries, in many cases it is required to move to a national level to obtain spatial and statistical data that are of consistent content, scale and quality for further analysis. Therefore, Spain was selected for further examination.

Citrus Fruit, Total Area Harvested (Ha)	Year			
	1999	2000	2001	2002
European Union (15)	556,894	559,262	556,110	558,346
France	2,974	2,405	2,264	2,287
Greece	58,350	60,800	61,000	61,050
Italy	177,677	177,717	177,599	176,659
Portugal	27,858	27,809	28,197	27,300
Spain	290,035	290,531	287,050	291,050

National Level

Cropping data from Spain's *Censo Agrario 1999*, distributed by *Instituto Nacional de Estadística* (INE, 1999) were used to identify areas of greater density of citrus production. The following map identifies the region of Valenciana as a primary area for analysing citrus production.

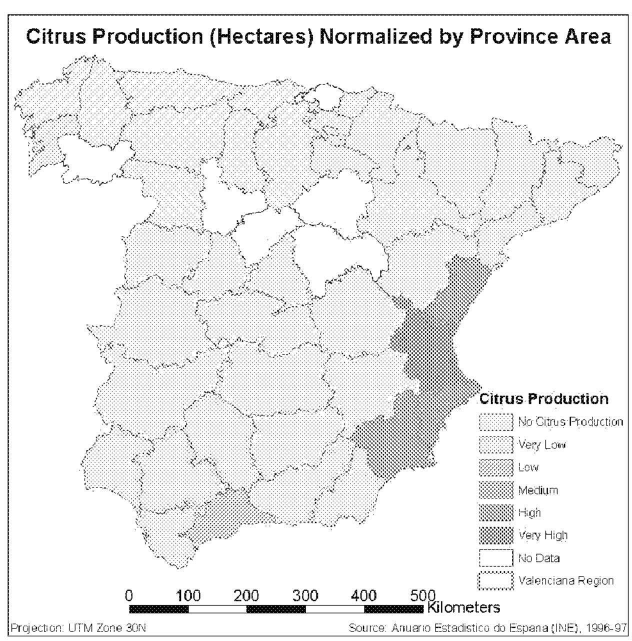


Figure A4.1. Initial distribution of citrus production for all of Spain.

As can be seen in the maps above, the Valenciana region has one of the highest concentrations of citrus production within Spain. Valenciana encompasses 67% of the national citrus production (as seen in the cropping statistics table below (INE 1999)).

	Citrus Production		
Province	Hectares	% of Region	% of Spain
Castellón/Castelló	37,505	23%	15%
Valencia/Valencia	90,673	55%	37%
Alicante	36,037	22%	15%
Valenciana Region	164,215	100%	**67%**
Spain Total	246,527		

The citrus-intensive portions of Valenciana fall within the extent of the R4 and D6 scenarios as depicted in the FOCUS Surface Water Sceanrios report, shown below.

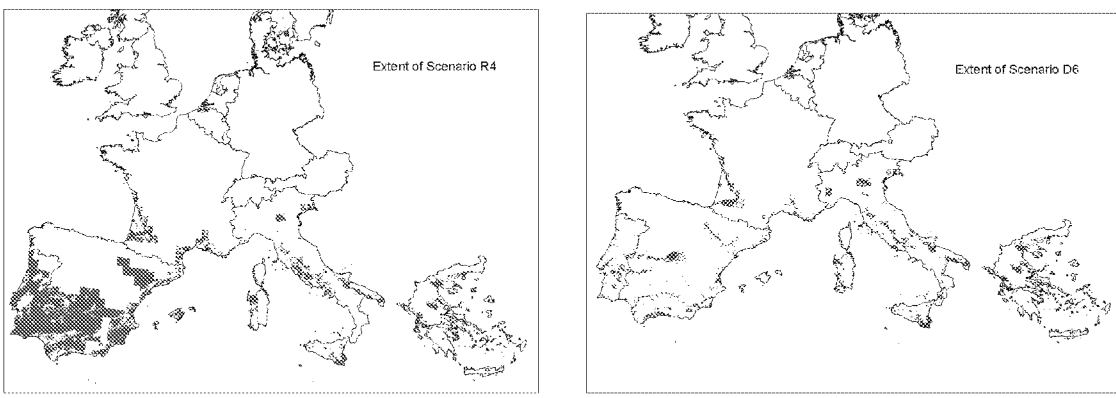


Figure A4.2. Extent of R4 and D6 scenarios

<u>Regional Level</u>

A more detailed view of the Valenciana region to locate citrus production using crop statistics at the *municipio* level (NUTS5) is shown below. The NUTS5 crop statistics were also obtained from the *Ministerio de Agricultura, Pesca y Alimentacion* (MAPA). Using this information, a suitable area within the Valenciana region was identified that corresponded with existing high-quality satellite imagery, acquired at an appropriate time to identify citrus (winter). The area covered by the satellite image is considered the "study area" and can be further examined using high resolution data sets for land cover, hydrology and other environmental data sets.

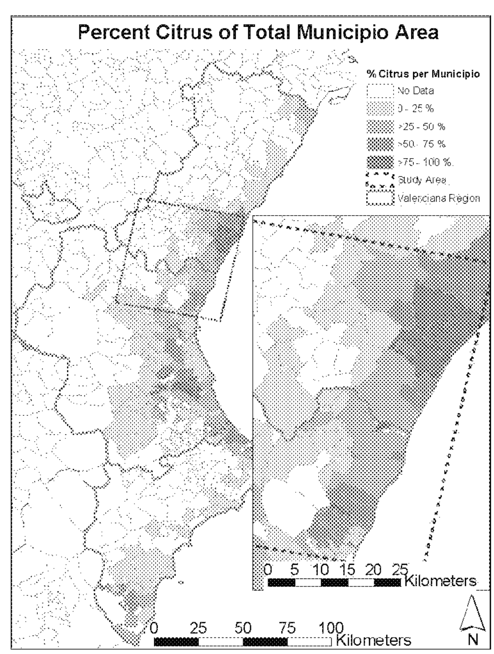


Figure A4.3. Refined location of citrus production in the entire Valenciana region

Local Level

Finally, the CORINE land cover data set was used to verify the spatial location of tree crop production in the area of greatest citrus production as defined using the crop statistics at the *municipio* level. This area (located north of the city of Valencia) is examined in relation to the possible satellite image footprints. Note that the CORINE land cover does not have a separate class for citrus, so the 'orchards and small fruits' class must be used. The following map shows agricultural production within the Valenciana region:

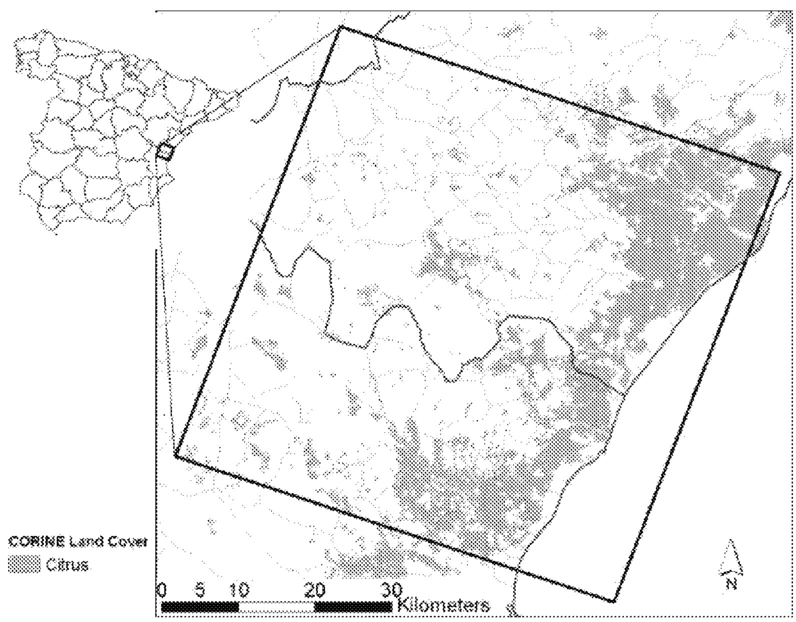


Figure A4.4. Final location of intensive citrus production in the Valenciana region

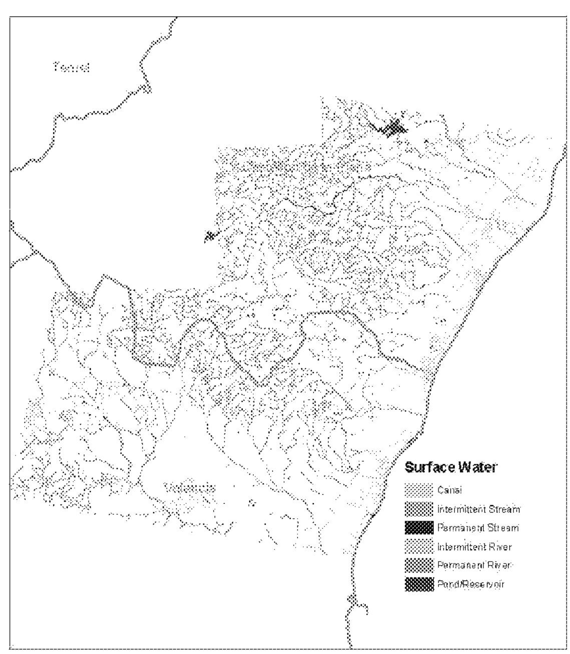


Figure A4.5. Surface water (1:25 000 scale) in the Valenciana region from MTN25 digital data

Once a refined study area had been selected, detailed hydrology was obtained from Spain's *Centro Nacional de Información Geográfica* (CNIG) using their MTN25 digital product. The data were provided in digital format and contain hydrology at a scale of 1:25,000. Hydrology for the study area is mapped in the following figure. This shows variations in hydrologic density, water body classes (streams, rivers, canals, ponds, reservoirs), and water body state (permanent vs. intermittent).

The MTN25 is the digital data used to create the 1:25 000 scale topographic maps, and was considered the best available surface water data set in spatial form.

A4.3.2 Analysis - Drift PEC Calculation

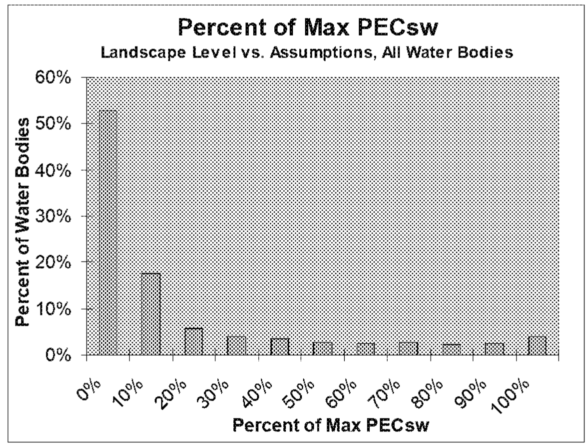
To provide detailed landscape data, a multi-spectral (20 metre) satellite image was acquired from the SPOT 2 satellite covering approximately 261,000 hectares on land (SPOT, 2000). The image was acquired on February 23, 2000. This image was classified specifically to identify citrus orchards. The classified land cover data were combined with the detailed hydrology (the MTN25 data) and the resulting data sets were analysed in a Geographic Information System to quantify the spatial relationships between citrus and surface water.

For the drift PEC analysis, a total of 3,719 water bodies were examined for drift loadings from citrus. For each water body, sampling points were placed along the perimeter every 10 meters. The drift estimation examined how much of the perimeter is exposed to spray drift in each of eight directions, and to what degree that perimeter is exposed based on distance to crop (i.e., what % of the maximum drift rate according to the FOCUS drift calculator). If a water body had 100% of its potentially exposed perimeter directly adjacent to citrus (within 3 metres), then the water body would have the maximum PEC calculated by the FOCUS drift calculator for that direction. The estimation of drift PEC's examined over 1.3 million individual measurements from the sampling points placed along the perimeter of each water body.

A4.3.3 Results - Landscape Drift PEC Calculation

The following charts illustrate how often the 3,719 water bodies in this citrus-intensive landscape exhibited the assumptions used in the FOCUS drift calculator (using a 3m distance to crop). These charts show that of all water bodies, relatively few (<5%) exhibited the assumptions that the entire water body is maximally exposed to citrus, which would result in a landscape-level PEC equal to 90-100% of the maximum FOCUS PEC. This chart also shows that over 50% of the water bodies in the area had no drift loadings.

The spatial analysis of drift loadings used the standard FOCUS method to determine the maximum PECsw based on crop type (i.e., it used the appropriate regression parameters for citrus). Since the same water body width and depth assumptions were used in both the calculation of the maximum *and* for the landscape-level analysis, the comparative results are independent of water body characteristics. The 'percent of maximum PEC' allows the water body characteristics to be removed from the comparison, thereby focusing solely on the influence of the landscape. The landscape factors that affect final estimated PEC's include the amount of citrus within 100 metres that may provide drift loadings, the distance at which that citrus is located, and the wind direction from which the loadings would occur.



Selected percentiles of the results (percent of maximum PEC) can also be reported, as an estimated PEC was computed for each water body and direction combination. Results for the most vulnerable water body classes (small streams and canals) are presented below. While a few water bodies exhibit the maximum characteristics in the landscape (100% cropped around perimeter, directly adjacent), the 90th, 75th and 50th percentiles show that the majority of the water bodies have much reduced exposure.

Fraction of Maximum PEC Based on Landscape Analysis								
WB Class	Water Body State or Width	Scenario Width	Selected Percentiles of Percent of Max PEC					WB/ Dir
			50th	75th	90th	95th	99th	Count
Streams	Permanent	1 m	0.00	0.21	0.62	0.72	0.83	224
	Intermittent	1 m	0.00	0.00	0.25	0.58	0.95	17008
Canals	<1m	1 m	0.11	0.36	0.69	0.82	1.00	1896
	1-3m	1 m	0.24	0.71	0.94	1.00	1.00	4480

A4.4 Step 4 Exposure Assessment

The same set of assumptions used in the Step 3 simulations regarding the surface water framework was employed as a starting point for the maximum PEC in Step 4 calculations with the following exception: the upstream catchment is ignored because the entirety of the landscape is considered and a highly conservative assumption is made that all citrus plantations are treated simultaneously with the same product. It was also assumed that the water bodies simultaneously derived drift loading from the worst-case wind direction. This necessarily exaggerates the scale of exposure and, therefore, risk. The drift data used to estimate exposure were also based on the BBA spray drift data where application to tree crops is made using mist blower equipment. In citrus, treatment of insecticides is more typically made using hand applied equipment, and drift from such treatments will be substantially lower than that from mist blowers. The assessment can therefore be considered to be conservative.

The maximum PEC derived from Step 3 run-off scenario modelling was 1.18 ∝g/l. The maximum PEC derived from Step 3 drainage scenario modelling was 1.54 ∝g/l.

It should be noted that the exposure assessment for the run-off scenario includes relatively conservative assumptions regarding the contribution to exposure from processes and applications occurring within the upstream catchment. Where FOCUS Step 3 data are used as a 'worst-case' benchmark within broader landscape assessments it may be appropriate to separate the upstream contribution or influence on exposure to ensure the direct influence on drift of natural mitigation within the landscape is reflected in a more meaningful manner.

The Step 3 exposure profiles demonstrate that the worst case PEC's are derived from a drainage scenario in which the upstream contribution or influence is considered negligible and the primary route of entry is clearly drift. Therefore, the following results are provided with reference to the maximum PEC value that coincides with a drift event at the immediate edge-of-field within the drainage scenario. This format of presentation enables very rapid identification of circumstances considered to provide sufficient natural mitigation of drift to demonstrate safety. TER values based upon a maximum PEC of 1.54 ∝g/l are:

	Minimum TER	Required mitigation (reduction in exposure, fraction of maximum PEC)
Fish LC_{50} (96 h static mortality):	85	0.85
Aquatic invertebrate EC_{50} (48 h static immobilisation):	62	0.62

Where *required mitigation* = TER / 100.

The prevalence of circumstances under which a fraction of ″ 0.85 reduction in exposure can be readily identified that would lead to a demonstration of safety for fish is highlighted in shaded cells in the table below.

Fraction of Maximum PEC – Reduction in Exposure for Safety to Fish								
	Water Body	Scenario	Selected Percentiles of Percent of Max PEC					WB/ Dir
WB Class	State or Width	Width	50th	75th	90^{th}	95th	99th	Count
Streams	Permanent	1 m	0.00	0.21	0.62	0.72	0.83	224
	Intermittent	1 m	0.00	0.00	0.25	0.58	0.95	17008
Canals	<1m	1 m	0.11	0.36	0.69	0.82	1.00	1896
	1-3m	1 m	0.24	0.71	0.94	1.00	1.00	4480
Note: Shaded cells represent sufficient reduction in exposure to achieve minimum TER								

As can be seen, sufficient natural mitigation exists within the landscape to enable summary conclusions to be reached regarding risks to fish. TER values <100 predicted for different water bodies are:

- Permanent streams: limited to ″ 1% of relevant water bodies
- Intermittent streams: limited to ″ 5% of relevant water bodies
- Irrigation canals (<1 m wide): limited to ″ 5% of relevant water bodies
- Irrigation canals (1-3 m wide): limited to ″ 25% of relevant water bodies

By far the most predominant water bodies are streams, representing 73% of the systems within the usage landscape. Of these, 98.7% are intermittent systems that would be unlikely to support fish populations or obligate aquatic or univoltine invertebrate species. It should be noted that other aquatic vertebrates (e.g. amphibians) may live in intermittent streams, even though the model organism (test species) to assess the risk for all aquatic vertebrates is fish. Ecotox test species are indicators of risk for a wide range of species and not just those very similar to the test organism. Regardless, even for these intermittent streams, the stream representing the 95^{th} percentile PEC has sufficient natural mitigation to give a TER > 100 (i.e., a landscape reduction equating to 58% of the Step 3 PEC). In other words, less than 5% of the intermittent streams have TER values <100 for fish, and risk in more than 95% of streams would therefore be considered acceptable for any amphibians present as well.

Canal systems are considered of lower ecological relevance as they would be characterised as intermittent systems that would be highly dynamic with water provided to smaller systems only as demanded. Again, such small, intermittent systems would be unlikely to support fish populations or obligate aquatic or univoltine invertebrate species. While amphibian species may be present, the likelihood compared to natural streams is lessened due to the lack of substrate and raised concrete construction of these small irrigation canals..

Although it can be demonstrated that risks to fish are highly mitigated by naturally existing margins between citrus and water within the landscape and the characteristics of the most closely associated water bodies further mitigate against risk to fish, the most sensitive species are aquatic invertebrates and, as a consequence, they must also be considered.

The prevalence of circumstances under which a factor of ″ 0.62 reduction in exposure could be readily identified that would lead to a demonstration of safety for aquatic invertebrates is highlighted in shaded cells in the table below.

Fraction of Maximum PEC – Reduction in Exposure for Safety to Aquatic Invertebrates								
	Water Body	Scenario	Selected Percentiles of Percent of Max PEC					WB/Dir
WB Class	State or Width	Width	50th	75th	90th	95th	99th	Count
Streams	Permanent	1 m	0.00	0.21	0.62	0.72	0.83	224
	Intermittent	1 m	0.00	0.00	0.25	0.58	0.95	17008
Canals	<1m	1 m	0.11	0.36	0.69	0.82	1.00	1896
	1-3m	1 m	0.24	0.71	0.94	1.00	1.00	4480
Note: Shaded cells represent sufficient reduction in exposure to achieve minimum TER								

As can be seen, sufficient natural mitigation exists within the landscape to enable summary conclusions to be reached regarding risks to aquatic invertebrates. TER values <100 predicted for different water bodies are:

∞ Permanent streams: limited to ″ 10% of relevant water bodies

∞ Intermittent streams: limited to ″ 5% of relevant water bodies

∞ Irrigation canals (<1 m wide): limited to ″25% of relevant water bodies

∞ Irrigation canals (1-3 m wide): limited to ″50% of relevant water bodies

To assess the impact of a no-spray label restriction, the water body class with the greatest exposure (canals) was re-processed in the GIS with a 5-metre no-spray buffer implemented. These results show that the reduction in exposure for a 5-metre no-spray buffer (when compared to the standard 3-metre crop distance), is such that all canals now have a TER > 100 for fish (reduction factor of " 0.85) and aquatic invertebrates (reduction factor of " 0.62):

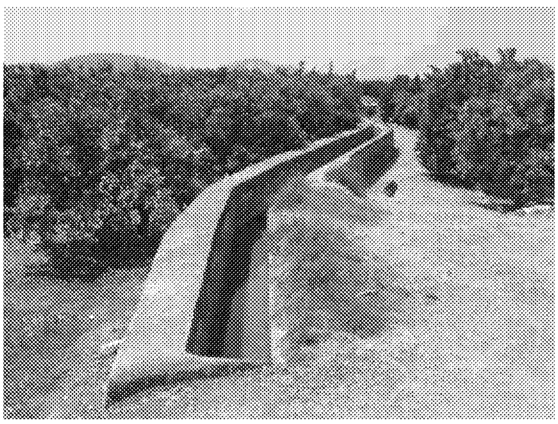
Fraction of Maximum PEC – Reduction in Exposure for Safety to Fish and Aquatic Invertebrates Ratio of 5-metre no-spray buffer PEC to Max PEC (at 3 meters)								
	Water Body	Scenario	Selected Percentiles of Percent of Max PEC					WB/Dir
WB Class	State or Width	Width	50th	75th	90th	95th	99th	Count
Canals	<1m	1 m	0.08	0.23	0.41	0.48	0.55	1896
	1-3m	1 m	0.15	0.42	0.54	0.57	0.57	4480
Note: Shaded cells represent sufficient reduction in exposure to achieve minimum TER								

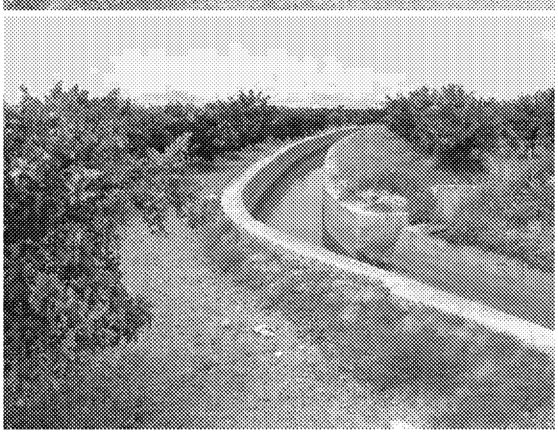
While in retrospect a 5-metre buffer could have simply been applied at Step 3, it cannot be known at the start of a potential Step 4 approach whether refined exposure will indeed reduce the needed buffer until the assessment is complete. In the case study for Valencia, one water body class (canals) remained unprotected without an imposed no-spray buffer. However, valuable information was gained, and a refined strategy for further understanding can be developed. Firstly, the landscape assessment helped to target the specific situations of concern regarding exposure to drift, in this case, the canals class of surface water. It also gave confidence that other water body classes were not of significant concern for fish and aquatic invertebrates. The Step 4 assessment suggests areas of further investigation to better understand the potential exposure of the target water bodies; such as increased flow rate in the canals when flowing for irrigation purposes, the potential impact of narrow (sometimes elevated) concrete channels with vertical sides on drift deposition, method of spray application (air blast versus hand lance), and the applicability of BBA tables for drift.

The risk assessment strategy has been prepared on the basis of an assumption that drift is the most significant route of entry in both the run-off and drainage scenarios. For completeness, modelling was repeated eliminating drift loadings in order to demonstrate the significance of run-off and drainage loadings on their own. In both cases, these routes of entry were considered to result in acceptably low levels of exposure.

A4.5 Inclusion of Ecological Considerations

In citrus growing areas, the climate is such that natural surface waters are at best intermittent and often temporary, apart from the largest rivers that are regulated and/or receive inputs from waste water treatment plants. Citrus culture requires irrigation, and an extensive network of irrigation canals is typical for such areas. These are often concrete lined channels designed to move water with the minimum of loss, and water is only discharged into the channels during irrigation events (see images below). Considering their lack of substrate to support plant or animal growth, the high flow rates of water passing through the systems, and the highly intermittent timing of water content, these small irrigation ditches would not support extensive communities of aquatic organisms. Therefore ecological risk assessment is of low relevance to such systems and it can be concluded that use of the product is unlikely to result in long-lasting effects on aquatic ecosystems in citrus.






A4.6 Conclusions

In summary, after a Step 3 exposure assessment, acute risks remain for fish and aquatic invertebrates. The Step 4 approach was a consideration of more realistic spray drift loadings into the edge of field water bodies utilizing landscape-level information for an intense citrus growing area. This area was identified using a quantifiable site selection process, and analysed in a GIS to produce PECsw values for several thousand water bodies, with sub-grouping for various canal and stream categories. These PECsw values were used to determine a reduction factor based solely on the landscape, and the natural mitigation contained within it.

Step 4 exposure results show that for fish, sufficient natural mitigation exists within the landscape such that the number of water bodies with a resulting TER < 100 are less than 5% for all streams (permanent and intermittent) and irrigation canals (<1m wide). Irrigation canals (1-3 m wide) presented the most potential exposure, with less than 25% having a TER < 100. The same trend for water body classes exists for aquatic invertebrates as well, with slightly more water bodies not achieving the required TER of 100. The number of water bodies with a resulting TER < 100 are less than 10% for permanent streams, less than 5% for intermittent streams, while irrigation canals (<1m wide, and 1-3m wide) presented the most potential exposure, with less than 25% and less than 50%, respectively, having a TER < 100.

When a 5-meter no-spray buffer was introduced for canals (the water body class with greatest potential exposure), all canals had a sufficient reduction in exposure (compared to the standard 3-meter assumption) to achieve a TER ≥100 for both fish and aquatic invertebrates.

Based on the landscape-level exposure analysis, irrigation canals have the greatest amount of potential exposure. Considering their lack of substrate to support plant or animal growth, the high flow rates of water passing through the systems, and the highly intermittent timing of water content, these small irrigation ditches would not support extensive communities of aquatic organisms. Therefore ecological risk assessment is of low relevance to such systems.

The Step 4 examination aimed at acute risk for fish and aquatic invertebrates showed that, for an intense citrus producing area, the potential exposure to surface water varies across the landscape and across water body types. The presence of natural buffers in the landscape show that a large number of streams and canals have PECsw values lower than the Step 3 values, resulting in TER values > 100 for these water bodies. Also, when a 5m no-spray buffer was implemented in the GIS, the number of water bodies with TER < 100 was eliminated. Irrigation canals had the greatest amount of potential exposure, but these types of water bodies will have less relevance for the ecological risk assessment. The ability to identify areas, or water body types, with greater or less potential exposure allows for a refined assessment of ecological risk.

References

CNIG, 2000. *Centro Nacional de Información Geográfica*, C/ General Ibáñez de Ibero, 3 Madrid, Spain 28003, Tel.: +91 - 597 9514, Fax: +91 - 553 29 13, Internet: http://www.cnig.es/.

FAO 2002, FAOStat, Food and Agriculture Organisation of the United Nations (www.fao.org)

FOCUS Drift Calculator, version 1.1, a component of SWASH, version 1.1 (9 Apr 2003). Available for download from http://viso.ei.jrc.it/focus/index.html.

INE, 1999. *Censo Agrario 1999*, *Instituto Nacional de Estadística*, Paseo de la Castellana, 183, Madrid, Spain 28071, Tel: +91 583 91 00, Fax: +91 583 91 58, Internet: http://www.ine.es/.

MDC, 1992. CORINE Land Cover. European Topic Centre on Land Cover (ETC/LC), Environmental Satellite Data Centre. MDC Environmental Satellite Data Centre, Miljodatacentrum I Kiruna AB, PO Box 806, SE-981 28 Kiruna, Sweden, Tel: +46 0980-671 70, Fax: 0980-671 80, Email: mdc@mdc.kiruna.se, Internet: www.mdc.kiruna.se.

SPOT, 2000. SPOT Image Corporation, 1897 Preston White Drive, Reston, VA 20191, USA, Tel: 703.715.3100, Fax: 703.648.1813, Internet: www.spotimage.com

Opinion of the Scientific Panel on Plant protection products and their Residues on a request from EFSA on the Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment

(Question N° EFSA-Q-2006-063)

adopted on 13 December 2006

SUMMARY OF OPINION

The PPR Panel presents an opinion on the Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment (hereafter: the *Report*).

Within the European Union, harmonised approaches for conducting aquatic exposure assessments have been developed. These are documented in the FOCUS Report on Surface Water Scenarios (FOCUS, 2001). The assessment of the Predicted Environmental Concentration (PEC) in surface water has been designed as a stepwise approach. The Step 1 accounts for an 'all at once' worst-case loading of a water body. The Step 2 calculation accounts for real application patterns. Step 3 performs an estimation of the PEC using realistic worst case scenarios taking into account agronomic and climatic conditions relevant to the crop, and a selection of typical water bodies. Ten scenarios for the compartment surface water have been designed, which collectively represent agriculture in the EU. Finally, Step 4 was originally envisaged to estimate the PEC based on specific (local) situations, which could be used on a case-by-case basis (FOCUS, 2001). The FOCUS Landscape and Mitigation group set out to develop a strategy for Step 4 and to review the state of the art in risk mitigation measures; to propose harmonised approaches to incorporate mitigation measures or refinements in the scenarios; and develop a listing of data that would help to reduce uncertainties particularly at the 'landscape level' of surface waters.

When comparing this *Report* with the FOCUS Surface Water ($_{SW}$) scenarios (FOCUS, 2001) the most important changes are:

- Risk assessment is extended to field scale with multiple edge-of-field situations but is not recommended to cover full landscape scale (catchments);
- Exposure reductions through current mitigation approaches are proposed and quantified for several exposure routes (spray drift, surface runoff, and drain flow);
- Several methodologies are proposed to incorporate modelling refinements and mitigation effects in the proposed Step 4 exposure assessment. This can be executed by (1) refinements of the input parameters in the existing FOCUS scenarios of the Step 3 approach of FOCUS$_{SW}$, or (2) by performing risk assessment outside the existing FOCUS$_{SW}$ approach (development of new scenarios, probabilistic modelling, catchments scale modelling, and use of monitoring data);
- Methods and data are described for (1) refinements of Step 3 model parameters based on landscape factors and (2) recommendations for development of new methodologies;
- It is proposed that ecological aspects be taken into consideration in risk assessment.

The PPR Panel considers the *Report* as a very useful overview of available and potential risk mitigation measures and their respective contribution to reducing exposure. The PPR Panel appreciates the broad view of the *Report* and the magnitude of the work completed.

On the other hand, the PPR Panel does have some comments on the content of the *Report*:

- The PPR Panel wishes to stress the differences in nature of the various mitigation measures and refinement options explored in the *Report*. Some of the proposed options may cause a change in the geographic applicability. The PPR Panel recommends that in such cases the percentage of agricultural land that is "protected" should be estimated.
- The PPR Panel would like to stress the general need to further improve the validation of the exposure models and especially of the new elements of the exposure models that are needed for the refinements. The validity should be assessed for a representative range of pesticides and relevant field conditions.
- There is no discussion of uncertainty and how to characterise it. Therefore, the PPR Panel recommends that a systematic treatment of uncertainty should be added to the *Report.*
- The PPR Panel is of the opinion that the methodology for landscape selection is not always well defined and that the possibility of different approaches in the selection procedure of the landscape type could result in different risk assessment results.
- The PPR Panel wishes to point out that the proposed opportunities for refined risk assessment provided by ecological and ecotoxicological considerations are actually base conditions for risk assessment at higher tier levels, rather than opportunities for refinement.
- The PPR Panel has some concerns about the need for extra data and methods which are not always available and on the fact that some possibly important exposure routes are not taken into consideration, e.g. emission by air and exposure from non spray applications.
- The PPR Panel agrees with the recommendation that refinement of the risk assessment at the higher tier should not take the form of a different risk assessment strategy and should remain at the field level as currently is.
- The PPR Panel does not agree with the statements concerning the maximal mitigation of spray drift, surface runoff and erosion, and drain flow (Recommendation 6). An alternative recommendation for spray drift is proposed.
- The PPR Panel proposes a revision of the recommendations on how to apply probabilistic methods to refine assessments.

The PPR Panel appreciates the inclusion of examples of refined risk assessment which are worked out in the *Report* as illustrations for risk assessment but has some remarks and comments on their methodology.

The PPR Panel also gives some comments on the proposed methodologies ("Boxes") in Volume 2 and gives some proposals for revision.

Based on the remarks given above the PPR Panel has concluded that the *Report* is a very promising vision for higher tier approaches to risk assessment but that it needs to be revised before it can be accepted as guidance to be used in an appropriate and consistent way by risk assessors.

Key words: FOCUS Landscape and Mitigation, surface water, plant protection products, pesticides, FOCUS Surface Water, higher tier assessment, refinement, mitigation, run off, spray drift, vegetated buffer, drain flow, landscape scale, uncertainty, probabilistic methods.

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BACKGROUND

The FOCUS Steering Committee identified the need to develop guidance on higher tier exposure assessment and the implementation of mitigation measures in the reasonable worst-case assessment developed at FOCUS Surface Water ($FOCUS_{SW}$) Step 3 (FOCUS, 2001). In June 2002 a working group was established to review potential approaches to higher tier surface water exposure assessment taking into consideration application of mitigation measures. As for other FOCUS groups it was formed by members coming from the MS regulatory authorities, academia and the industry.

The remit of this group was to review the current state of the art, where possible recommending approaches that could be implemented forthwith, and to also produce recommendations where further work is needed. The working group considered approaches suitable for supporting listing in Annex I, but also those that could be applied in risk assessments to support national registration.

The formation and main work of the group preceded the splitting of responsibility for risk assessment and risk management between the European Food Safety Authority (EFSA) and the European Commission DG-SANCO.

In May 2005, the FOCUS group presented the final document (SANCO/10422/2005, version 1.0), hereafter referred to as the *"Report"* collecting its main conclusions and proposals. In April 2006, the DG SANCO informed the EFSA that it does not intend to consult the EFSA's PPR Panel considering this to be not directly linked to DG SANCO's managerial responsibilities but suggested to consider the *Report* under the EFSA's self-tasking regime.

Before incorporating the guidance given in the *Report* into the current procedure of risk assessment of pesticide active substances, the PRAPeR unit in the EFSA therefore requests the independent opinion of the PPR Panel as detailed above.

TERMS OF REFERENCE

The Scientific Panel on Plant Protection Products and their Residues (PPR Panel) of EFSA is asked for an opinion on the document "Landscape and mitigation factors in aquatic ecological risk assessment" (The Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment) with respect to:

- **the state of the art in the fields of environmental science and agronomic technology;**
- **the scientific robustness of the proposed effect of mitigation measures on the reduction of exposure of surface waters to pesticides;**
- **the applicability of the procedures proposed to incorporate the consideration of mitigation measures to the risk assessment performed in the context of Directive 91/414/EEC and**
- **any other issues, mistakes, bias and recommendations for its improvement the PPR Panel identifies during the examination of the document.**

ASSESSMENT

9 1. INTRODUCTION

In the framework of Directive 91/414/EEC regarding the placing on the market of plant protection products, methodologies and approaches have to be developed in order to carry out an appropriate environmental exposure assessment and to evaluate the risks involved with the use of pesticides. To accomplish that, the FOCUS (FOrum for the Coordination of pesticide fate models and their USe) was established under the auspices of DG SANCO. Its aim was to develop standardised methods for the evaluation of different aspects concerning risk assessment of pesticides with regard to ground water, surface water, degradation kinetics, air, etc. In the case of surface water, the work of these expert groups resulted in a report with detailed methods and recommendations for a stepwise approach whereby the first steps represent simple methods of risk assessment based on a worst case approach and limited input values. Further steps represent more realistic approaches but they are more complex and need much more additional data, experimental support and more skilled modelling experience. Such considerations resulted in a 3-step methodology for risk assessment of pesticides to surface water (FOCUS, 2001). However, application of this stepwise methodology to most pesticides leads often to a 'not acceptable risk' due to the conservative approach of the proposed methodologies. It was the opinion that a higher tier approach including landscape and mitigation factors would be appropriate, giving a much better estimation of the risks under realistic circumstances. In order to obtain a kind of Step 4 approach for the evaluation of the risks of pesticides to surface water a 'FOCUS Landscape and Mitigation' group was formed with the task of proposing such a higher tier approach. This resulted in a *Report* of two volumes: Volume 1 gives an extended summary and recommendations; Volume 2 gives detailed technical reviews with all information supporting the conclusions of Volume 1. When comparing this *Report* with the $FOCUS_{SW}$ scenarios (FOCUS, 2001) the most important changes are:

- Risk assessment is extended to field scale with multiple edge-of-field situations but stays excluded from true landscape scale with interconnected water bodies (catchments);
- Risk reductions for current mitigation approaches are proposed and quantified for several exposure routes (spray drift, surface runoff, drain flow);
- Several methodologies are proposed to incorporate modelling refinements and mitigation effects in the proposed Step 4 exposure assessment. This can be executed by (1) refinements of the input parameters in the existing FOCUS scenarios of the Step 3 approach of $FOCUS_{SW}$, or (2) by performing risk assessment outside the existing $FOCUS_{SW}$ approach (development of new scenarios, probabilistic modelling, catchments scale modelling, and use of monitoring data);
- Methods and data are described for (1) refinements of Step 3 model parameters based on landscape factors and (2) recommendations for development of new methodologies;
- Ecological aspects in landscape assessment are proposed to be taken into consideration, such as (1) defining typical species' communities for different water body types for refining the effects assessment, and (2) possible mitigation of effects by recovery of the affected populations, both internal (through reproduction within the affected water body) and external (through immigration from neighbouring water bodies).

10 2. EVALUATION OF THE FOCUS LANDSCAPE AND MITIGATION REPORT

The PPR Panel has made a thorough review of the FOCUS Landscape and Mitigation Report, hereafter referred to as the "*Report*". The *Report* is considered to be a very useful overview of available and potential risk mitigation measures, and their respective contribution to reducing exposure. It provides comprehensive analyses of relevant literature. Broader issues like assessments on landscape scale and the incorporation of further ecological data are also discussed.

2.1. STRUCTURE OF THE REPORT

The *Report* is well structured and the terminology is in accordance with the nomenclature of the other FOCUS reports. The PPR Panel is fully aware of the efforts which have gone into its preparation. The inclusion of all the supporting information into Volume 2 improves the readability of Volume 1. The examples of refined risk assessment are considered to be necessary as part of Volume 1 because they illustrate the scientific basis on which sometimes very difficult Step 4 exposure assessments have to be performed. The PPR Panel has no suggestions on the structure of the *Report*, the approach of the problem formulation and the general concept.

2.2 GENERAL REMARKS

2.2.1. Applicability of the proposed approach for risk assessment of pesticides

The PPR Panel notes that the remit for the *Report* is fairly narrow and assumes understanding of the underlying risk model. The PPR Panel observed that the FOCUS working group has widened the scope of the *Report* to include consideration of catchment scale risk assessment and ecological considerations. The PPR Panel appreciates the broad view of the *Report* and the magnitude of the work completed.

The PPR Panel wishes to stress the differences in nature of the various mitigation measures and refinement options researched in the *Report*.

- Some measures are clear-cut changes in product formulation, dosage, intended crop, or restrictions in area of use. These measures do not require manipulation of models.
- Some measures are to be taken during applications and are materially changing the emission. These mitigation measures affect only a single parameter within the models.
- Some measures concern consideration of typical agricultural conditions: soil type, buffer zones, and the receiving environment. These measures require changes in more than one parameter, revision of the modelling tools, or correction of the earlier modelling results with expert judgement values.
- One refinement option concerns the creation of new scenarios.
- Further refinement options concern alternative modelling approaches, such as catchment scale modelling, that require aligned effect assessment approaches and decision making criteria.

It has to be noted that the protection goals should be clearly, and *a priori*, defined (what type and level of effects to be avoided for which organism, on which level of biological organisation, on which geographical scale) so that there is a clear and constant benchmark against which the predicted (and refined) exposure can be compared.

The PPR Panel wishes to point out that a number of the proposed refinement measures (again, especially those which rely on replacing standard scenario values by specific ones or on creating new scenarios) may result in assessments which are rather limited in their geographical applicability, due to the specificity of the new input data. The PPR Panel thus recommends that new scenarios and changes to standard scenarios are not only well documented and justified, but that there is also an assessment as to the geographical applicability of the refinement (see Recommendation 9).

The proposed Step 4 assessments include a wide variety of methods and data. The PPR Panel is of the opinion that specific mitigation measures should be described more precisely, such as the design and maintenance of buffer zones or the details of drift reducing techniques. An example might be the very specific "practice" descriptions developed in the US by the USDA Natural Resource Conservation Service[2].

2.2.2. The need for extra data and methods

In the PPR Panel's opinion much information necessary to perform all proposed refinements is missing or unsatisfactory. The PPR Panel notes that the available information has increased considerably since the compilation of the *Report* and that it should be possible to integrate these new data into the higher tier approach. On the other hand, the given reduction figures (for example for drift reduction assessment) were mostly determined under experimental conditions but are sometimes not achievable in practice. There can be differences between proposals of mitigation measures and their application in practice. The solution of this problem (the choice of the maximum reduction) is left to the risk manager on a "case-by-case" approach. This is probably not the best option because it is up to the risk assessor to establish the necessary and achievable exposure reduction efficiency on a sound (possibly probabilistic) basis.

2.2.3. The need for validation

Refinement of exposure assessment in Step 4 may imply modification of input, structure or output (*via* post processing) of the exposure models used in Step 3. The PPR Panel comments in detail on the different refinement proposals elsewhere but would like to stress here the general need to further improve the validation of the exposure models and especially of the new elements of the exposure models that are needed for the refinements e.g. including buffer strips for PRZM runoff modelling, including photolysis in TOXSWA, etc.

The validation of a model has to be based on comparisons between model output and field measurements. In such a comparison not only the model itself is tested but always also the procedures for estimating the model input parameters (e.g. irradiated water-sediment studies using artificial light for estimating photolysis rates in water). Both models and such procedures are unlikely to be universally valid. Therefore the validation has to be assessed for a representative range of pesticides and relevant field conditions.

2.2.4. Treatment of uncertainty

As a general principle, characterising uncertainty should be a fundamental part of risk assessment, and this applies to both deterministic and probabilistic assessments. The specific remit for the Re*port* p. 11) includes to *"develop a listing of data that would help to reduce uncertainties in the higher tier exposure assessment"*. The *Report* does include many recommendations on types of data that may be used in higher tier assessment, but it contains very little discussion of uncertainty[3] and none on how to characterise it.

This is, for example, illustrated by the selection of climate parameters for the scenario identification process for drainage simulations (Vol. 1, Table A1.3; p. 76). The recommendation of the climate parameters (annual average recharge or average winter rainfall; annual average temperature/autumn temperature/spring temperature) includes several empirical assumptions that are subject to uncertainty which can result in different exposure. There is basically a need for a case by case assessment that should always be accompanied by a list of uncharacterised sources of variability, and an assessment of their influence on the end-point calculation.

The PPR Panel recommends that a systematic treatment of uncertainty should be added to the *Report*. Specifically, the PPR Panel recommends that the *Report* should be revised to include:

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[2] See: http://www.nrcs.usda.gov/Technical/efotg/

[3] Uncertainty is mentioned in relation to interpretation of monitoring data (Vol. 1 p 44 and Vol. 2 p 188), estimation of recharge based on climate parameters (Vol. 1 p 76), and characterisation of toxicity (Vol. 1 p 54 lines 22-26 and Vol. 2 p 326 lines 13-17).

- A systematic evaluation of uncertainties associated with key quantitative statements in the *Report*, including statements about the potential impact of mitigation measures on exposure;
- A requirement for every Step 4 assessment to contain a systematic evaluation of uncertainties, comprising a list of known uncertainties and a quantitative or qualitative evaluation of their impact on the assessment conclusions;
- Guidance on methods for systematic identification and evaluation of uncertainties. The PPR Panel recommends that this should include reference to probabilistic methods in which uncertainty is quantified using probability distributions, sensitivity analysis where the assessment is repeated with alternative input data or assumptions to assess their influence, and qualitative methods such as tabulating sources of uncertainty (for an example, see EFSA, 2006a).

The PPR Panel emphasises the importance of these additions, as they are essential to provide risk managers with an indication of the confidence that can be placed on the results of Step 4 assessments.

2.2.5. Difficulties with the implementation of the landscape analysis

The PPR Panel is of the opinion that the methodology for landscape selection is not always well defined. The possibility of different approaches in the selection procedure of the landscape type can result in different risk assessment results ("best choice" versus "realistic worst case"; "typical" versus "worst case"). Such developments are not possible in lower tier assessment procedure (Step 3).

For national approval it is expected that the assessment is part of a risk model that contains both a benchmark for the protection level for the environment, a methodology that addresses these endpoints in a scientifically adequate manner, a level of agricultural practice that is considered legitimately representative, and flexibility to incorporate mitigation measures that can be enforced and will be complied with within the Member State. Here, not all measures will prove feasible.

2.2.6 Incorporation of ecotoxicological characteristics into (new) assessment scenarios

In the context of incorporating eco(toxico)logical characteristics into assessment scenarios, before implementing the proposals of the *Report* concerning ecological aspects, a clear definition of the protection goal(s) of the assessment becomes crucial. The PPR Panel is of the opinion that the conclusion formulated in Vol. 2, section 3, that under Directive 91/414/EEC, unacceptable environmental effects are broadly defined as *"long term repercussions for the abundance and diversity of non-target species"* is a misconception. The quoted text does not define what constitutes unacceptable environmental effects, but defines a particular Member State liability regarding the use of plant protection products. It is correct to deduce that *"long term repercussions for the abundance and diversity of non-target species"* is in itself an unacceptable influence; but it is incorrect to deduce that it is the only unacceptable influence to be considered at risk assessment For example, short term effects may also be a basis for regulatory action. The Directive 91/4141/EEC, as amended, simply does not specify to the full extent what constitutes an unacceptable influence for every criterion in the "Uniform Principles".

The bulk of the data and refinement options discussed in the *Report* concern the estimation (and its possible refinement, i.e., reduction) of the exposure of surface waters to pesticides. Ecological considerations can be grouped into three aspects:

1. Some of the ecological considerations relate also to the refinement of exposure, such as discussion on the effects of aquatic plants on the dissipation of dissolved pesticides (**Recommendation 20**).

The PPR Panel agrees in principle that such factors might influence exposure but wishes to point out that for instance the occurrence of aquatic plants or riparian vegetation is likely to be dependent on many local factors. The impact of such absorption on ecotoxicological effects would also depend e.g. on the relationship between the speed of absorption versus the speed of effects occurring, i.e. the impact is both dependent on substance properties and on the way the habitat within the water body is assembled.

The more such refinements are combined in a risk assessment, the more site-specific the result may be, and accordingly limited in its applicability to wider areas. The presence of macrophytes is influenced by many factors, and can thus hardly be assumed as a mitigation factor available on national scale for all water bodies of a type which, in addition, needs to be defined in a way that farmers can recognise it, in order to be suitable for use in effective risk mitigation through labelling. In this context, the PPR Panel wishes to highlight the *Report's* statement made on p. 22 of Volume 1: The measure must be practicable with a reasonable possibility of enforcement. It should be kept in mind that the authorisation of plant protection products operates on a national level, with the label instructions being possibly the only measure of conveying rules or information of sub-national applicability to the end user of the product. The *Report* should be reviewed again as to which refinement options are suitable to be applied on national scale.

2. The definition of ecological characteristics of the surface water scenario (such as different species communities) is also proposed as a refinement option. This is mainly related to a supposed difference in sensitivity between ecosystems, based on variation between ecosystems in resilience (i.e., the ability to return to a previous state, after an impact on population levels and number of species present has occurred).

   With regard to the statement on sensitivity, it should be pointed out that the focus the *Report* puts on resilience suggests that resistance is of less importance and effects are acceptable, as long as the system shows resilience and returns to the desired state. This line of reasoning is understandable given the misconception at the start of the section 3 in Vol. 2 that puts the focus only on long-term effects. However, already in Vol. 1, section 6.2.1 it is stated that, based on state-of-art science, thresholds for effects are often similar. While the latter statement refers to data from stagnant water micro-/mesocosms only, with the extrapolation step to real field still missing, there are no such data concerning running water bodies such as small streams with their different species communities.

   Also, “resilience” of water body types (i.e., their species communities) is an array of many different, often species-specific adaptations to disturbances of natural origin. They are crucial in ensuring reproduction and survival for many species. Such adaptations include life stages able to migrate (e.g., adults of aquatic insect larvae), high reproduction potential, or durable resting stages able to survive phases of unsuitable conditions (e.g., eggs resistant to drying out). The respective mechanisms vary between species, and they may only be available at a certain time (e.g., reproduction to produce durable eggs before a typical dry period in summer; metamorphosis of larvae into flying adults once per year). The timing of an impact is thus equally crucial as the number of, and time between, different impacts.

   Pesticide-related impacts may occur any time, also during phases when recovery mechanisms are not available to affected species. The potential for recovery therefore depends not only on timing, number and degree of disturbances (both natural and pesticide- related) but also on the ecological traits of the respective species. From this it follows that recovery can not be estimated without referring to a certain species with a certain set of ecological traits. For pesticide-related impacts, it can not be taken as being readily available for risk mitigation when needed. The PPR Panel is thus of the opinion that temporal water bodies are not by definition (as implied in **Recommendation 18**) more resilient also to pesticide impact.

In that respect a differentiation in ecological characteristics appears unlikely to provide applicants and regulators with sufficient discriminatory power to differentiate between intended uses, and/or to provide clear and practicable use instructions as risk mitigation measures.

Therefore, the PPR Panel can support **Recommendation 18** only in the broader sense that improved knowledge on the interaction of ecological characteristics and pesticide impact in different surface water body types could be helpful in linking the assessment under Directive 91/414/EEC to other EU legislative frameworks like the Water Framework Directive (WFD, EU, 2000). It could also help in the determination of critical effect values and the assessment of (semi-)field studies. A major condition for this is more work on improving the understanding of toxic effects on organisms other than *Daphnia*, e.g., univoltine aquatic insect species of running water bodies; impact of short-term exposure also on long-term endpoints and preconditions and processes of recovery (Liess, 2002).

3. As a specifically ecotoxicological aspect, the *Report* discusses the lack of knowledge on toxicokinetic and –dynamic knowledge, and the problems of relating time-varying exposure in the field (as predicted) with ecotoxicological experiments run under specific (mostly constant) exposure regimes.

   It has traditionally been common practice to separate the handling of the exposure studies from the (eco)toxicity evaluation and only link them in a Toxicity-Exposure-Ratio (TER). The PPR Panel is of the opinion that an improved interaction between fate and ecotoxicology evaluations through all tiers of the assessment brings significant opportunities to increase the usefulness of the existing data and scenarios, and to thus improve the risk assessment (EFSA, 2005a). This applies also to improved use of toxicokinetic information which can already be gained from existing study types. The PPR Panel thus appreciates the respective efforts made in this *Report*, and recommends that these approaches are investigated more systematically.

In conclusion, the PPR Panel wishes to point out that the opportunities for refined risk assessment provided by ecological and ecotoxicological considerations (as phrased in Vol. 1, section 6.1), are actually base conditions for risk assessment at higher tier levels, rather than opportunities for refinement.

The PPR Panel therefore supports the general approach of the *Report* that ecological considerations (and improved relevant knowledge) at the landscape level could eventually improve realism of risk assessments. The most comprehensive attempt to summarise current knowledge in terms of the effect of pesticides in the field is presented in SETAC (2005). This publication is based on a workshop organised by the EU and SETAC in 2003. As this document is now published the PPR Panel suggests making use of the information.

Therefore, and with the caveats outlined above, the PPR Panel in principle agrees with the approach behind **Recommendations 17, 18, 19, 20, 21 & 22** that more knowledge on ecological characteristics of different water body types could eventually be useful for improving risk assessments but that more research is needed first. The PPR Panel realises that current higher tier approaches need to be reconsidered accordingly.

The *Report* also mentions the possibility of reducing the uncertainty (assessment) factors when more data become available (Vol. 1, p. 54 and Vol. 2, p. 326). The quoted publication, however, does not provide clear rules for this. The use of uncertainty factors in risk assessments is always a difficult point because the approach so far has been empirical and subjective. The PPR Panel suggests that the *Report* could usefully refer to the PPR Panel's recent opinions on uncertainty (assessment) factors for the aquatic environment for lower and higher tiers (EFSA, 2005b & 2006b) where objective and statistical methods were proposed at least for the issue of reducing the factor when additional data from other species are available.

Related to this, the PPR Panel wishes to observe that the standard organisms used to evaluate the ecotoxicological effects of a pesticide are not always useful for extrapolation to the situation for more sensitive species or species of different life histories, and that the conditions of some micro-/mesocosm studies are not comparable with some special conditions in the field for which refinements are implemented in the *Report's* scenarios. In order to extrapolate effects to more realistic environmental conditions and autochthonous species the use of specifically designed (field) studies appears essential. A review for that can be found in SETAC (2005).

2.2.7. Field scale versus landscape approach

The PPR Panel agrees to **Recommendation 1** that ecological risk assessments should remain at the field scale. The authors of the *Report* concluded (Vol. 1, p. 16) that it would be mandatory to include all stressors, i.e., input from multiple pesticides at different times and locations, in catchment- and landscape-scale assessments.

2.2.8. Remarks concerning missing emission routes

The PPR Panel has some concerns that some possibly important exposure routes are not taken into consideration in the *Report*. Some of these routes can be handled in the future because some important studies and documents have been published since the publication of the *Report* such as the EFSA opinion on dust drift by NSA ("non spray applications" like granules and seed treatments) (EFSA, 2004) and the FOCUS Air Report (FOCUS, 2006). Other missing exposure routes are inputs by groundwater and wastewater contamination.

2.2.9. Referring to non available methods and/or data

The PPR Panel wants to point out the difficulties when a reference is cited but not (yet) available. There are several examples:

- p. 29: line 13, line 29 and line 33
- p. 31; line 5
- p. 42; line 17
- p. 46; line 27
- p. 142; line 14

11 3. SPECIFIC COMMENTS

The specific remarks by the PPR Panel follow the order of the document.

3.1 COMMENTS ON "GENERAL PRINCIPLES" (VOL. 1, SEC. 2)

The PPR Panel has noted that the *Report* has considered various aspects of up scaling risk assessment (Vol. 1, section 2.3) and finally recommends that refinement of the risk assessment at the higher tier should not take the form of a different risk assessment strategy and should remain at the field level as it currently is. Therefore the PPR Panel supports this **Recommendation 1** and wishes to add some comments as to the reasoning and robustness of science that has lead to this recommendation:

- While a more integrated assessment of time and space including multiple stressors is claimed to be out of scope when it concerns the exposure assessment of a product, a certain amount of time (for internal recovery) and also space (for external recovery), is assumed available free from stress factors when it concerns effect assessment. Since multiple stressors such as repeated use of the same and the use of other plant protection products, as a result of Good Agricultural Practice (GAP) and crop rotation, are part of the common knowledge of the decision framework, they should be considered as boundary conditions also for the field-scale assessments where they are equally relevant (especially if a certain level of effects from one application/product is considered acceptable).

- The *Report* states that catchment-scale assessments are not suitable at EU level but may be appropriate at regional or Member State level, provided that the approach has been sufficiently validated. However, the validation status of available models was not demonstrated in the *Report*. Further, if the approach is really appropriate at the Member State level, this would mean that the predictive capability of existing tools was indeed sufficient, and that the boundary conditions set by multiple stressors may have been dealt with adequately. However, this has not been elucidated in the *Report.*
- However, the PPR Panel foresees that in future, modelling tools will become helpful in assessing whether the requirements for water quality set under the Water Framework Directive (EU, 2006) are met beyond the field scale.

3.2. COMMENTS ON "RECOMMENDATIONS FOR MITIGATION OF RISK TO THE AQUATIC COMPARTMENT UNDER 91/414/EEC" (VOL. 1, SEC. 3)

The PPR Panel does not fully agree with all statements in **Recommendations 2**. The grouping into categories must be made according to real field situations and a classification into 5 groups is considered to be exaggerated and not relevant because it can be different for different kinds of mitigation measures. Therefore a case by case grouping for each mitigation group is considered to be more appropriate.

The PPR Panel agrees with **Recommendation 3** about the process to implement certain measures into risk assessment but wants to express reservation because the level of protection remains a risk management matter.

The PPR Panel accepts also the statements of **Recommendations 4 and 5** but proposes some other wordings (change *"mitigation"* to "mitigation possibilities" in Recommendation 4; delete *"high"* on line 11, p. 23) and wants to draw attention to the necessity of more information.

The PPR Panel does not agree with the statements in **Recommendation 6** concerning the differentiated maxima of mitigation (Vol. 1, Table 5) which are given and discussed in Vol. 1, sections 3.4 (spray drift), 3.5 (surface runoff and erosion) and 3.6 (drain flow) based on the following considerations:

a) The ability to achieve a maximum reduction in **spray drift** of 99% will depend on integrating several mitigation techniques under ideal conditions. In practice this maximum will not be possible due to variations in wind speed and direction as well as changes in boom height above the crop. Selecting a nozzle to give a coarse spray, especially an air-induction nozzle will significantly reduce drift, particularly when used with a buffer zone of at least 1 metre. The extent to which a combination of mitigation techniques interact is less well understood, but reductions of at least 75% are attainable in the field. Similar techniques are used for both arable and orchard crops, although buffer zones need to be wider for the latter, and where a windbreak is present, it will also filter drifting droplets. Without being complete, Table 1 lists factors that are considered by the PPR Panel to have an important effect on the reduction level. Although a lot of these factors may have a cumulative effect when applied simultaneously, no data were presented which demonstrate that these rates could be achieved under GAP. It is therefore the opinion of the PPR Panel that risk reduction can not reach the proposed maximum drift reduction under practical conditions because many of the factors can only be considered in specific situations. The PPR Panel does not agree that a maximum drift reduction of 99 % has been demonstrated and is attainable in practice and is of the opinion that the figure of 99% should be changed to 85%, based on the data shown in Table 1 (Van de Zande *et al.*, 2006; Kop, 2001; personal communication G.A. Matthews, 2006, and expert judgement of the PPR Panel).

b) The 90% maximum mitigation value for **runoff** ignores the *Report*'s own summary in Vol. 2 Table 1.8. No evidence for 90% reduction of weakly soil-sorbed pesticides is presented, except for the obvious case of elimination of use. Thus the "90%" value proposed is possible only with strongly-sorbed pesticides, i.e., pesticides with a *Koc* value of at least 2000 l/kg (see *Report* Vol. 1, p. 78, line 19).). Even in the case of strongly-sorbed pesticides the PPR Panel was not given enough information describing the specific circumstances under which the 90% or similar mitigation occurs. It is well known that the effect of a vegetated buffer strip is strongly dependent on a number of factors such as slope, soil type, area ratio of field to buffer, etc. These factors are not explored in the *Report* but all buffer experiments are simply correlated with buffer width. The PPR Panel is of the opinion that unless the specific conditions *necessary* for a given reduction are provided, the proposed mitigation factor is not defensible. Part of the problem may stem from what appears to be an assumption in the *Report*, namely that sediment load reductions observed from mitigation measures are the same as runoff water volume reductions, which is not the case.

c) The PPR Panel has also concerns about the proposed additional options for mitigating risk for **drain flow** proposed in Vol. 1, section 3.6. In this section it is assumed that the presence of field drains is the 'cause' of any pesticide losses and thus a restriction of use on 'drained soil' will give 100% reduction. The PPR Panel does not agree that this will be the case because it is the inherent soil conditions (seasonal water logging within soil layers) that provide the potential for rapid transport of pesticides to surface waters. Installation of field drainage in such soils usually depends on both crop requirements and socio-economic constraints but, if installed, merely results in slightly increased losses. Pesticides applied to slowly permeable seasonally wet soils that do not have any field drains installed will still be lost preferentially by rapid transport routes because the soil will be much more subject to saturation runoff losses during the late autumn and winter months. The work on drainage restrictors reported in Vol. 2, section 1.5.3.7 shows that any restriction of the effectiveness of field drains will have virtually no effect on losses of more mobile compounds. The PPR Panel therefore suggest that any mitigation option involving blanket restrictions will need to be applied on the basis of soil type, rather than field drainage practice, for example *"do not apply to soils susceptible to periodic water logging because of slow permeability or rising ground water tables"*. The PPR Panel suggests changing Table 5 (Vol. 1) accordingly. The PPR Panel does not agree with the proposed reduction of 100%.

Table 1: Factors considered as having an important effect on the reduction level (no completeness assumed).

Factor	**Description**	**Change in Drift**	**Compliance**
Spray quality	Coarse*	Up to 85% reduction Air Induction (AI) nozzles provide 75% drift reduction. But possibly up to 96% reduction.	Already adopted by many farmers. Air induction nozzles significantly reduce drift. But efficacy may be reduced if too coarse a spray is used, especially with contact acting pesticides.
Boom height	50cm above crop	Drift is increased, if boom is higher than 50 cm, especially at faster forward speeds.	Modern sprayers have better boom stability, but boom height will vary while spraying.

Wind speed	<5km/h >1km/h	Drift increased when wind speed exceeds 5 km/h, but there is also a risk of smaller droplets travelling further if no wind.	Gusts can occur. Wind direction can also change, affecting extent of drift.
Forward speed	5 – 7 km/h	Drift increased by 4 – 6 % for each increase of 3km/h	Trend to higher speed speeds for rapid treatment when conditions are favourable
No-spray 'buffer' zone	Width set for pesticide	Up to 85% drift reduction esp. if with tall vegetation. Unmown grass with wild flowers provides best drift reduction.	Acceptable especially with conservation farming. Buffer width can be reduced with Drift Reduction Technology.
Hedgerow	Must be higher than crop without major gaps.	Drift reduction affected by porosity of hedge, allowing air flow and filtration of droplets.	Accepted as windbreak, but not all fields have hedges.
Downward-directed air assistance	Only use if crop acts as a filter of spray	Drift reduction depends on crop canopy. May increase drift if poor retention of spray. Up to 70% drift reduction with low-drift nozzle and boom 50cm above crop	Expensive equipment, so adopted by only a small proportion of farmers.

* assumes operating pressure at the nozzle ensures that the spray quality is coarse

3.3. COMMENTS ON "INCORPORATING REFINEMENTS AND MITIGATION INTO EXPOSURE ASSESSMENT AT STEP 4" (VOL. 1, SEC. 4)

3.3.1 Comment on new scenario development

The PPR Panel agrees with the **Recommendations 7 and 8** on the applicability of Step 4 modelling as support for proposals of exposure mitigation. Nevertheless, the PPR Panel agrees that there are likely to be some cases where development of new scenarios may be necessary to address specific uses not properly covered by the $FOCUS_{SW}$ Step 3 scenarios. It also agrees with **Recommendation 9** that, in such cases, the procedures for overlaying soil, climate, slope and cropping data outlined by the $FOCUS_{SW}$ Scenarios Group should be followed. However, the PPR Panel does not agree that the procedure outlined in Annex A1 of Volume 1 is an appropriate example. The reasons for this are given in section 3.7 of this opinion where an alternative generic method is suggested.

3.3.2 Comments on probabilistic modelling

The *Report* recommends (**Recommendation 10**) that probabilistic methods *"can be applied as one of the approaches to refining assessments of exposure and/or at Step 4 and that this conclusion is equally applicable for the aquatic and terrestrial compartments"*. The PPR Panel strongly recommends that this recommendation should be revised to emphasise that probabilistic assessments should only be accepted when they are conducted in an appropriate manner. This is essential to avoid potential pitfalls and disadvantages (some of which are listed in Vol. 1, p. 41) and to ensure the results are reliable. It would also be relevant to add that probabilistic methods can be applied to effects assessment as well as exposure.

Although there is not yet any officially accepted guidance on the appropriate use of probabilistic methods for EU pesticide risk assessments, the reader can be referred to some useful sources of advice, including some already cited in Vol. 1. The PPR Panel recommends that the *Report* should also advise readers to follow the US EPA's general guidance on criteria for acceptance of Monte Carlo assessments (US EPA, 1997).

The FOCUS work group implies that, in the short term, probabilistic methods will be limited to quantifying variation in weather between years (Vol. 1, p. 42 and, more strongly, Vol. 2, p. 180). The PPR Panel suggests that it might be equally desirable and feasible to quantify variation in application dates, since runoff depends strongly on the time interval between application date and rainfall events. It should be added that, in any probabilistic assessment, those parameters which remain deterministic should be fixed to appropriate values, which are selected so as to achieve an appropriate overall degree of conservatism in the results. This implies that the fixed parameters should be kept at the values currently used in Step 3, unless appropriate work is done to calibrate the conservatism provided by different values at Step 4.

Another factor currently inhibiting the uptake of probabilistic methods is the lack of established approaches and criteria for using probabilistic outputs in decision-making. The PPR Panel recommends that efforts be made to fill this gap. Until this is done, it will be necessary for probabilistic outputs to be considered case-by-case.

In Volume 2 of the *Report*, the description of types of probabilistic output on p. 175 (lines 1-6) is difficult to understand (e.g. it is not obvious what the *"vertical lines"* refer to unless one has seen graphs of this type). Also, only two of the possible options for probabilistic output are described.

It is important in probabilistic assessments to distinguish between uncertainty and variability and treat them appropriately (US EPA, 1997). Currently the *Report* is vague about this. For example, Vol. 2, p. 176 says it may be necessary to address some of the more significant uncertainties through a form of probabilistic modelling, and then says (apparently as an example) that Monte Carlo is often used to address the impact of variability (lines 8-10). This should be revised to state more clearly that probabilistic methods can be used to quantify variability and/or uncertainty. Currently, most references to probabilistic modelling in the *Report* appear to relate to quantifying variability. The PPR Panel recommends that consideration should also be given to quantifying uncertainty to provide confidence intervals on the outputs, especially if some of the inputs are subject to substantial sampling uncertainty (i.e. estimated from small datasets) or measurement uncertainty.

In Vol. 2, p. 177, lines 19-20, repeating FOCUS calculations with different sets of parameter values are described as a "manual" probabilistic assessment. These calculations would more properly be described as sensitivity analysis or scenario analysis. It cannot be regarded as "probabilistic" unless the process reflects in some way the relative probability of alternative parameter values (e.g. by sampling from distributions as in Monte Carlo).

3.3.3 Comments on catchment scale modelling

Recommendation 11, not to recommend routine inclusion of catchment modelling into ecological risk assessment is supported by the PPR Panel but the recommendations that *"catchment scale modelling may be useful in linking the requirements under 91/414/EC with those of the Water Framework Directive"* is not clear to the PPR Panel. How could product assessment and monitoring be linked if there are no tools available that allow catchment scale assessment for pesticide registration? However, the PPR Panel does support the notion that the assessment at authorisation should function as a tool for meeting the requirements under the WFD (EU, 2000) and is of the opinion that further research in that area should be carried out. The PPR Panel therefore recommends that the development of validated catchment modelling approaches, linked to Step 3 scenarios should be addressed as a priority to support European level regulation and catchment monitoring requirements.

The *Report* proposes refinements of the FOCUS Step 3 catchment parameterisation in Vol. 2, p. 151, **Box 12** and p. 109 (the factors to change with respect to the catchment size and its characteristics). In view of the simplistic and relatively non-mechanistic way in which the FOCUS Step 3 scenarios calculate inputs from the up-stream catchment, the PPR Panel does not agree that such modifications are scientifically acceptable. Instead the PPR Panel proposes that any refinements of Step 3 scenarios using catchment characteristics should be carried out using a more realistic and mechanistic catchment model in a similar way to the example outlined in A2 of the *Report*.

3.3.4 Comments on chemical monitoring data

Recommendation 12 is on the use of appropriate monitoring data. For refined higher tier approach the consideration of existing monitoring data is supported by the PPR Panel but only when the uncertainties mentioned in section 4.3.4. of Vol. 1 are taken into account. However, the PPR Panel would like to point out that the *Report* does not reflect the state of the art of the surface water monitoring programmes carried out in the different EU Member States. Neither does the document take into account the EU requirements on environmental quality standards (as indicated by the Chemical Monitoring Activity - CMA) carried out in DG Environment, or the Water Framework Directive (EU, 2000) implementation concerning both chemical and biological data requirements. The accessibility of the data produced by the application of the above directives is undergoing testing by each Member State through the informatic tool Water Information System Environment where pesticide measurement together with biological data will be available for all the stakeholders at the EU level.

Following these remarks, the PPR Panel considers that monitoring data on the quality of surface water reported at EU level are probably useful as background information, both in large scale and in preliminary or complementary assessment of the water quality. However, none of the monitoring schemes appears suitable to detect short-term contamination peaks (such as caused by runoff events) which can have, nevertheless, significant population-level effects (Liess & Von der Ohe, 2005). Therefore, the data will be not be applicable in certain cases, such as for specific pesticide risk assessments (where they cannot replace either exposure or effects assessment), or for modelling studies and their parameterization, mainly at catchment scale. For specific monitoring studies a detailed and appropriate sampling plan is necessary, possibly incorporating sampling (both biological and chemical) regimes which are event-triggered (such as from runoff or spray drift entries) rather than at regular intervals (where short-term events may be overlooked).

3.4. COMMENTS ON "METHODS AND DATA FOR DESCRIBING AGRICULTURAL LANDSCAPES" (VOL. 1, SEC. 5)

The PPR Panel agrees with **Recommendations 13, 14, 15** concerning the need for full justification and documentation of the approach used to generate and analyse data, the rationale for site selection and the methodology and data processing used in any geographical information system (GIS) analysis. It further recommends that any landscape analysis used to support Step 4 refinements should be clearly linked to the results from the Step 3 risk assessment and resulting problem formulation. The methods used should be appropriate for providing a more comprehensive and realistic set of exposure data for the proposed use for which the Step 3 scenario(s) have indicated a possible risk assessment problem.

The PPR Panel also strongly endorses **Recommendation 16** that any site selection process should include an appropriate examination to place the selected site in its broader EU-wide use context. It recognises that Vol. 2, section 2.3.5 of the *Report* provides such examples but believes they are too specific to a single issue, namely spray drift. Issues related to drainage and runoff are likely to be more complex as the additional factors of soil and climate need to be included. The PPR Panel therefore recommends that any site-selection process should include an EU-wide context setting step using the generic methodology outlined in Vol. 1, section 3.7 (Identification of new scenario locations at Step 4).

The PPR Panel recognises that the data sources listed in the *Report* are comprehensive and reflect the state of the art at the time of the *Report*. However, the PPR Panel also agrees that the availability of datasets is a rapidly evolving and changing area. The PPR Panel believes that availability of state of the art pan-European data is critical for establishing confidence in any Step 4 refinement based on analysis of agricultural landscapes and therefore proposes that a procedure be established to compile and maintain state of the art pan-European databases to support European level risk assessment for plant protection products.

3.5 COMMENTS ON "RECOMMENDATIONS FOR FURTHER WORK" (VOL. 1, SEC. 7)

The PPR Panel agrees with **Recommendations 23 and 24** that new working groups are needed to further improve the landscape analysis, modelling, mitigation approaches and ecological characteristics. In this case they should address the open questions raised in this and in other relevant reports (SETAC, 2005). In addition the suggestion in **Recommendation 25** to develop complementary approaches for terrestrial systems is welcomed by the PPR Panel.

3.6 COMMENTS ON "IDENTIFICATION OF NEW SCENARIO LOCATIONS AT STEP 4" (VOL. 1, APP. A1)

The PPR Panel does not agree that the methodology described in this example is appropriate. Whereas, the PPR Panel does agree that the main climatic 'drivers' for pesticide losses *via* drainage or runoff can be identified, they are likely to be both route- (drainage or runoff) and model-specific and should only be identified after some sensitivity analysis has been carried out with the chosen model. In addition, the PPR Panel does not believe that the identified individual risk drivers can be combined in a simple probabilistic way assuming an equal impact from each of the factors and a normal distribution of the factors within the area of interest. The relative importance of any single climatic factor is likely to be highly variable depending on the interaction between compound physico-chemical properties and soil properties. The PPR Panel therefore does not consider it scientifically justifiable to adopt such a simplistic statistical approach to combine factors in the way demonstrated. Instead, the PPR Panel suggests that a more acceptable generic method for the development of new scenarios would be as follows:

- Use spatial cropping data and statistics to identify the area of interest for the proposed use.
- Identify the model-specific driving climatic variables using a sensitivity analysis of the appropriate environmental fate models.
- Map the spatial distribution of the identified climatic variables within the area of interest using the best available climatic datasets.
- Identify the model-specific driving soil (and slope) variables using a sensitivity analysis of the appropriate environmental fate models.
- Map the spatial distribution of the identified soil (and slope) variables within the area of interest using the best available soil and slope datasets.
- Overlay the spatial datasets to identify one or more combinations that represent real locations that combine the identified model-specific worst-case characteristics for drainage or runoff.

3.7 COMMENTS ON "EXAMPLE OF REFINED RA – FUNEN" (VOL. 1, APP. A2)

The PPR Panel consider that this example provides a very good illustration of how a significantly more refined type of risk assessment can be carried out at Step 4 by using a much more sophisticated modelling procedure to produce a range of PEC within a 'real' catchment that has close affinities with a specific $FOCUS_{SW}$ scenario. The strong points of the methodology are that:

- It demonstrates a direct link with the specific Step 3 scenario for which a risk was identified.
- It puts the problem FOCUS scenario into a 'real' context and provides time series of PEC within sub-catchments of similar size to the conceptual catchment of the FOCUS scenarios, as well as within larger sized sub-catchments.
- The extensive background data available for the catchment, together with its validated hydrology give a high level of confidence in modelled results.
- The comprehensive PEC results provided from the model can be considered in a probabilistic way and examined in detail to identify causes of significant concentration peaks. It thus provides a significantly improved basis for decision making.

However, the PPR Panel would also point out that:

- Not many catchments within Europe are currently characterised at this level of detail or linked to specific Step 3 scenarios.
- The example uses only four years of weather data to produce the PEC time series. Ideally, at least 20 years of data would be provided to ensure that extreme weather events were encompassed in the simulation.
- It is not clear whether the original D4 problem was related to input from spray drift or from drainage. Ideally, the problem formulation step would include such an assessment.

3.8 COMMENTS ON "EXAMPLE OF REFINED RA – BRIMSTONE" (VOL. 1, APP. A3)

Based on the provided information, the PPR Panel has serious doubts whether this example of a refined risk assessment is scientifically robust enough. These doubts are based on the concerns in the following paragraphs. It is possible that providing more information in a revised version would remove these doubts.

The refined risk assessment aims at refuting calculations for the D2-Brimstone scenario (i.e. FOCUS Step 3). The Brimstone-D2 scenario uses a 16-month weather series with 623 mm annual rainfall in the last 12 months which generated a worst case water recharge according to FOCUS (2001). Appendix A3 uses four approximately equal climatic classes (dry – medium – wet - very wet) with yearly rainfall of <625 mm, 625-750 mm, 750-850 mm and >850 mm respectively. So the D2-Brimstone scenario would be classified as a dry climate in Appendix A3 while FOCUS (2001) classified it as worst case with respect to recharge. This is a surprising difference for a risk assessor which is nowhere mentioned or discussed.

In the refined risk assessment, new scenarios were developed which imply that new soil profiles and new climate characteristics were selected. Appendix A3 shows that the 'dry' D2-Brimstone scenario generates a higher PEC than the very wet scenario for the soil that is most similar to the D2-Brimstone soil (i.e. Denchworth) in the refined risk assessment: the PEC for D2-Brimstone was 44 ∝g/L for an annual rainfall of 623 mm whereas the maximum PEC for the Denchworth soil in the refined risk assessment was 42 ∝g/L (maximum of 30 annual values) with a maximum annual rainfall of 1361 mm. This indicates that the selection and parameterisation of the soil profiles in the refined risk assessment had a larger influence on the outcome than the selection and parameterisation of the climate classes. Therefore the PPR Panel focussed its attention on the soil profiles.

For an adequate justification of the selection procedure of the soil profiles the PPR Panel considers more information necessary on the number of soil series within each class of soils and on e.g. the median and variability of the clay contents of a number of soil series at the vulnerable end of each soil class.

The D2-Brimstone soil-profile represents a 75th percentile worst-case for preferential flow in the Denchworth soil series (i.e. a 75th percentile clay content of 54%). The refined risk assessment uses also this Denchworth soil series (as a representative series of one of the five soil classes considered) but uses the average clay content from this series (i.e. 43%). So the change from 54 to 43% clay resulted only in a small change of the PEC (from 44 ∝g/L to 42 µg/L) despite a considerable increase of annual rainfall (from 623 mm to probably close to 1361 mm). This implies a large effect of this change in clay content on the PEC. There are two possible causes for this large effect: the change in clay content itself or a difference in the procedure of the MACRO parameterisation. The parameterisation for the D2-Brimstone soil profile has been based on MACRO calibration to measurements at the Brimstone experimental field (FOCUS, 2001). Appendix A3 refers to Brown *et al.* (2004) for the description of the MACRO parameterisation in the refined risk assessment. One of the most important MACRO parameters for pesticide leaching in structured soils is the aggregate half-width ("ASCALE"). Brown *et al.* (2004) indicate that this half-width was selected from basic descriptions of soil structure using rules proposed by Jarvis *et al.* (1997). On the basis of this, the PPR Panel considers the MACRO parameterisation of the D2-Brimstone soil profile to be of higher quality than the MACRO parameterisation of the Denchworth soil in the refined risk assessment. Appendix A3 and Brown *et al.* (2004) do not describe the values selected for parameters such as ASCALE as used in the refined risk assessment. So it is possible that the lower PEC values in the refined risk assessment have been caused mainly by a less reliable parameterisation procedure of MACRO rather than by a lower clay content. The former would be difficult to defend as a scientifically robust refined risk assessment.

3.9 COMMENTS ON "EXAMPLE OF REFINED RA- VALENCIA" (VOL. 1, APP. A4)

Example 4 of the *Report* (pp. 117-133) is a refined risk assessment for an insecticide (EC) to support listing on Annex I (EU) and national (MS) registration procedures for use in citrus. Step 3 calculation suggested potential concerns of acute risk for fish and aquatic invertebrates in the $FOCUS_{SW}$ scenario named R4 and D6. To refine this assessment the Step 4 calculation was then based on: (a) using spray-drift loading calculated according to FOCUS drift calculator; (b) spray-drift loading into the edge of the field water bodies categorized by GIS; (c) an agricultural landscape with the presence of citrus. The landscape-level PEC in each of the surface water bodies were calculated in this scenario.

The PPR Panel considers this landscape-level risk assessment (LRA) example a generic and broad approach easy to follow by model users in similar situations and easy to understand for the assessors. The stepwise approach and the down scaling from the EU to the regional scales are correct. The method developed on PEC_{sw} calculations for several thousand water bodies based on landscape is considered robust and valid. Nevertheless the PPR Panel believes that the example is lacking information to complete an acceptable landscape risk assessment. In fact the method reflects only slightly recommendations 13 and 14 of the *Report* and if this is due to text length constraints then basic information about the method and its application should be provided in the final *Report*. The PPR Panel recognizes a number of scientific data requirements in the present example listed below:

- Demonstrate that the conservative assumptions set are valid. While upstream dilution is clearly a conservative assumption, a predetermined day for the application time of the whole landscape cannot be a conservative assumption for long term exposure of surface water bodies. Because all parameters set in the scenario must be realistic and scientifically valid we expect the author of the risk refinement to furnish the measured or estimated data to support these assumptions. For old pesticides the actual use must be monitored by a farm survey; for the new substances the potential use can be predicted based on the agronomic characteristics of the area and crop (efficacy and pest phenology). The PPR Panel believes this is essential for a realistic assessment of the pesticide loading and of its application time in the scenario. For transparency the information must be included in the *Report*.
- Demonstrate the representativeness of the scenario and how it represents the European conditions (or Member State level in case of national registration). The PPR Panel recognizes that the scenario selection needs an appropriate statistical analysis itself and of the main factors affecting pesticide fate in this ecosystem. The site selection based only on GIS analysis of the citrus EU distribution is not exhaustive and doesn't necessarily represent the European characteristics of the citrus crop area cultivated in the whole of Europe (type of soil, irrigation, rainfall, temperature, hydraulic plan, plant distribution in the field, plant shape, soil slope). The minimum data requirement when developing citrus scenario must be in line with the $FOCUS_{sw}$ approach, that is, it must include information on parameters affecting the pesticide fate. The reader should recognize that the citrus scenario selected is representative because it covers representative properties in a greater area where the crop is cultivated.
- Calculate PEC for all the entry routes selected. The Valencia example considers only the drift as entry route of exposure to surface water bodies because of the result of FOCUS Step 3 and the information patched through satellite photographs. The PPR Panel disagrees with the above assumption because it demonstrates the low representation of the scenario chosen: citrus crops in EU-wide area must grow in well-drained soil and in intensive irrigation system, both factors affecting the drainage. The entire entry route should be assessed and if not present in one scenario an additional scenario must be included.
- Report the application technology used and how this affects the PEC calculation. Very often pesticide application in citrus crops is manual. The look up table of the FOCUS drift calculator does not include citrus crop, neither does the manual application. The PPR Panel

again recognizes that this agronomic aspect should be taken in account when exposure and risk are refined. For transparency reasons application of the technology and its consequences on pesticide drift should be demonstrated through calculation or measurement.

∞ Demonstrate the relevance of the water bodies and their vulnerability. To support the ecological considerations such as the statement on artificial channel reported in the example calculation, measurement or field scouting is mandatory. The use of monitoring data at this stage could be used for confirmation and for understanding the vulnerability of the whole area selected.

3.10 COMMENTS ON PROPOSED METHODOLOGIES IN VOLUME 2 ("BOXES")

The proposal to use time dependent sorption values for runoff and drainage (**Box 1**) is agreed by the PPR Panel, however not for the PRZM submodel because the scientific approach used for increasing sorption is inconsistent. To solve correctly the sorption process in soil the scientific representation should include its time dependence and the kinetics of sorption in conditions of equilibrium and disequilibrium. The proposed refinement with PRZM on *"entering a time series of sorption values with the time that permits the model to represent the time-dependent sorption in soil"* cannot be considered a scientifically valid approach. Reasonably the PPR Panel recognized this fact and recommends for comprehensive simulations the use of better tools available such as PEARL and MACRO 5.

Concerning the inclusion of photolysis in water and on plant and soil surface (**Box 2**) is for the PPR Panel no problem but practical and useful scenarios are not given. The PPR Panel is thus of the opinion that more guidance is needed to include photolysis into Step 4 exposure assessment.

The PPR Panel accepts the proposals formulated in **Boxes 3, 4 and 5** on respectively, the modelling of metabolites, the proposal for refinements for simulation of controlled release formulations or incorporation in soil (e.g. slow release) and the change of drift parameters in the drift calculator.

The PPR Panel does not agree with the proposal (**Box 6**) not to include dry deposition from air into the Step 4 scenarios. It is the opinion of the PPR Panel that conservative assumptions have to be made in the absence of satisfactory knowledge. In this context the PPR Panel would refer to the FOCUS (2006) and to previous EFSA opinions (e.g. EFSA, 2004).

Box 7 recommends performing a higher tier wash off study to refine the wash off rate constant for use in regulatory modelling. The PPR Panel considers a single study only acceptable if it can be demonstrated that this study was conducted under conditions that are conservative for the risk assessment. Otherwise there can be no reasonable certainty that the results of such a study can be extrapolated to all use conditions of the pesticide.

Box 7 refers furthermore to the FOCUS Step 3 procedure for estimating this constant (i.e. an equation based on correlation with the water solubility). Leistra (2005) reviewed this procedure and also the available wash off literature. He concluded that (i) the data on which this equation was based could not be retrieved from literature, and that (ii) this equation seems to overestimate the wash off. This implies that the approach in the FOCUS Step 3 procedure for estimating the wash off may not be conservative enough. The PPR Panel recommends therefore that the *Report* provides also guidance to revise the FOCUS Step 3 procedure for estimating the wash off rate constant in order to avoid overestimation of wash off in the risk assessment.

The PPR Panel accepts the proposed methodologies on the practical Step 4 refinements within the FOCUS modelling framework for respectively, the modification of PRZM runoff parameterization of runoff and erosion (**Box 8**). Given the PPR Panel's concern for the need for buffer design information, the change of PRZM runoff output to simulate the effect of buffer strips (**Box 9**) is not accepted (see comments above on the proposed mitigation amounts). The change of MACRO parameterisation for drainage (**Box 10**) is accepted by the PPR Panel. The PPR Panel agrees on the exclusion of colloidal transport for drainage (**Box 11**).

The PPR Panel has commented on the statements in **Box 12** concerning the high degree of conservatism for the Step 3 calculations of transport in water bodies (see comment in 3.3.3).

CONCLUSIONS AND RECOMMENDATIONS

The Scientific Panel on Plant Protection Products and their Residues concludes that the FOCUS Landscape & Mitigation Report can be considered as an extension of the FOCUS Surface Water Report because it is a higher tier (Step 4) assessment of the Step 1, 2 and 3 risk assessments in the latter report.

The *Report* gives an extensive overview of the state of the art in the fields of environmental science and agronomic technology related to the landscape and mitigation factors in aquatic ecological risk assessment. Nevertheless the PPR Panel wants to make some remarks on certain aspects treated in the *Report*:

- The *Report* gives only proposals and recommendations but not really a ready-for-use methodology giving a standard scenario for risk assessors. This kind of *ad hoc* approach without preliminary fixed rules for harmonisation is more or less based on a kind of expert judgment of the most realistic situations and conditions but lacking the discipline of the decision process of other FOCUS procedures. However, the PPR Panel is aware of the difficulties involved with the development of higher tier assessments and the impossibilities to implement a unique standard method for the multitude of possible mitigation measures and model refinements.
- Information necessary to accept the proposals to mitigate drift, drainage and run-off is often missing or unsatisfactory. E.g. in the case of runoff, most of the given reduction figures are determined in experiments whose conditions are not adequately described and whose relevance to real situations is not demonstrated. There can be differences between proposals of mitigation measures and their application in practice.
- The PPR Panel would like to stress the general need to improve further the validation of the exposure models and especially of the new elements of the exposure models that are needed for the refinements. The validation of a model has to be based on comparisons between model output and field measurements. In such a comparison not only the model itself is tested but always also the procedures for estimating the model input. The validation has to be assessed for the full range of pesticides and of relevant field conditions.
- The PPR Panel has some reservations on the use of uncertainty factors in the risk assessment process. This is always a difficult point because the approach is often empirical and subjective. The degree of uncertainty is also related to a kind of risk management which is often not scientific. Especially in this *Report* this aspect is more crucial because there is a close link with ecotoxicological aspects. The PPR Panel refers to its previous opinions on uncertainty (assessment) factors for the aquatic environment for lower and higher tiers (EFSA, 2005b & 2006b) where objective and statistical methods were proposed at least for the issue of reducing the factor when additional data from other species are available.
- The PPR Panel is of the opinion that the methodology for landscape selection is not always well defined. The possibility of different approaches in the selection procedure of the landscape type can result in different risk assessments.

- It is further the opinion of the PPR Panel that probabilistic methods are suitable for both effect and exposure assessment but it is necessary to apply these in an appropriate way.
- It is the opinion of the PPR Panel that a realistic effect assessment should include as well (i) long-term effects of short-term contamination (ii) interaction of the effect of toxicants with other stressors (competition, predation, environmental stressors) and (iii) recovery.
- The PPR Panel is of the opinion that there is a need for a better description when a field scale or landscape scale is needed from the point of view which the ecotoxicological effect is to be evaluated.
- The PPR Panel is concerned that some emission routes are not taken into consideration in the *Report*, e.g. non spray applications and emission by air.

In the following, the main conclusions and recommendations of the PPR Panel are provided:

1. The PPR Panel has given its comments on the 25 Recommendations in Volume 1 of the *Report*. The PPR Panel agrees on most of the proposed Recommendations in the *Report* but disagrees on the conclusions in **Recommendation 6** concerning the proposed maxima of mitigation (Vol.1, Table 5) for drift, surface runoff and erosion, and drain flow which are not accepted by the PPR Panel and other recommendations are proposed.
2. Before implementing the proposals of the *Report* concerning eco(toxico)logcial characteristics in assessment scenarios, a clear definition of the protection goal(s) of the assessment is necessary.
3. The more different (types of) refinements are combined in an assessment, the more site-specific the result may be, and accordingly limited in its applicability to wider areas. The *Report* should be reviewed as to which refinement options are suitable to be applied in product authorisations on national scale.
4. The PPR Panel is of the opinion that there is no information that temporal or ephemeral water bodies are not by definition (as implied in Recommendation 18) more resilient also to pesticide impact.
5. A differentiation in ecological characteristics appears unlikely to provide applicants and regulators with sufficient discriminatory power to differentiate between intended uses, and/or to provide clear and practicable use instructions as risk mitigation measures.
6. More research is needed on improving the understanding of toxic effects on organisms of different water body and life history types, including preconditions and processes of recovery.
7. Improved knowledge on the interaction between fate and ecotoxicology evaluations through all tiers of the assessment bears significant opportunities to increase the usefulness of the existing data and scenarios. This applies also to improved use of toxicokinetic information which can already be gained from existing study types. The PPR Panel thus recommends that these approaches be investigated more systematically.
8. With the caveats outlined above, the PPR Panel in principle agrees with the approach behind **Recommendations 17, 18, 19, 20, 21 & 22** that more knowledge on ecological characteristics of different water body types could eventually be useful for improving risk assessments but that more research is needed first. The PPR Panel realises that current higher tier approaches need to be reconsidered accordingly.
9. There is a need for training for implementations and for monitoring results for feedback into the risk model. In view of the extent and very technical nature of this document, the implementation of methods and recommendations in the *Report* requires that regular

training courses be held for MS authorities and registrants to illustrate the theory and provide practical experience in the evaluation of laboratory and field data using the software tools proposed in the *Report*.

10. There is a need for continuous (periodical) updating of developments in the methodology and data requirements.
11. There is a need for harmonisation of the different systems used by the member states (e.g., Focus drift calculator as standard for al drift effects).
12. The PPR Panel proposes to formulate advice to risk management on ecological protection goals in terms of critical effect values so that authorities can decide on field study results and translate backwards to lower tier benchmarks.
13. The Panel suggests providing clarity about the relationship between the Annex I risk assessment strategy and national decision making under the "Uniform Principles" and the resulting implications for risk assessment by Member States.
14. The Water Framework Directive (EU, 2000) assumes that use of pesticides in accordance with Directive 91/414/EEC will lead to compliance with the chemical standards (MAC and AA) of the WFD. However, the risk model under Directive 91/414/EEC is not capable of assessing this assertion: compliance at the local field scale does not guarantee compliance at the regional scale.
15. Comparison exercises or ring-tests should be organized to attain comparability of the results. Therefore, the PPR Panel recommends that ring-tests are carried out, where MS, registrants and other intended users derive surface water risk assessment scenarios for a series of substances and circumstances, to ensure that the proposed procedures in the *Report* are intelligible, robust and precise enough.
16. The PPR Panel recommends that the *Report* should be revised to include (1) a systematic evaluation of uncertainties associated with key quantitative statements in the *Report*, including statements about the potential impact of mitigation measures on exposure, and (2) a requirement for every Step 4 assessment to contain a systematic evaluation of uncertainties, comprising a list of known uncertainties and a quantitative or qualitative evaluation of their impact on the assessment conclusions.
17. The PPR Panel recommends that the guidance for systematic identification and evaluation of uncertainties should include reference to probabilistic methods in which uncertainty is quantified using probability distributions, sensitivity analysis where the assessment is repeated with alternative input data or assumptions to assess their influence, and qualitative methods such as tabulating sources of uncertainty (for an example, see EFSA 2006).
18. The PPR Panel wishes to draw attention to the fact that some of the refinement options considered in the *Report* may result in new or modified scenarios, which may have different geographic applicability compared to the existing scenarios of FOCUS Step 3. The PPR Panel therefore recommends the geographic applicability of each refined assessment should be evaluated by estimating the percentage of relevant agricultural land that it "protects", as was done for the original FOCUS scenarios.
19. The PPR Panel recommends that **Recommendation 10** of the *Report* should be revised to emphasise that probabilistic assessments should only be accepted when they are conducted in an appropriate manner, taking account of available guidance such as the US EPA's criteria for acceptance of Monte Carlo assessments (US EPA, 1997).

The PPR Panel wants to express its appreciation of the production of the *Report* and considers it as an important milestone of higher tier risk assessment. The *Report* is the result of an enormous effort to achieve a level 4 risk assessment based on recent developments in the fields of landscape modelling, ecotoxicology, probabilistic approaches, etc. This is finalized in the description of a series of new approaches for risk assessment which are very promising. On the other hand, this has lead to a number of only partly resolved issues which are not yet ready for risk assessment application for several reasons (lack of data, no validation, uncertainties, etc.). These aspects are discussed in the *Report* but precise conclusions on the practical applicability are sometimes unclear and therefore not yet ready for risk assessment application. The PPR Panel shares the strong recommendations in the *Report* to support further scientific research in this field.

Considering the above remarks the PPR Panel finds that the *Report* is lacking some clarifications on the way level 4 risk assessment should be carried out. Therefore the PPR Panel recommends identifying clearly all the methodologies which are possible at the moment with an acceptable degree of applicability and certainty for risk assessors. This includes that, in practice, a certain number of methodologies, which are given in Vol. 2 (the so called "Boxes"), have to be worked out in such a way that they can be used as guidance documents for the risk assessor. The PPR Panel is also of the opinion that some extra guidance ("Boxes") is needed in order to clarify some confusions which have to be resolved (e.g. runoff calculation of upstream applications). Also a precise table of all input parameters and modelling functions which have to be used for the calculation of the endpoints is crucial for the transparency and reproducibility of the assessment.

The PPR Panel is of the opinion that the approaches which cannot be applied in an (as yet) approved way, because of missing satisfactory scientific support and validation, can not be accepted as level 4 risk assessment without further investigations. The PPR Panel is of the opinion that a lot of efforts is still needed for the practical application of these methodologies. Special attention must be paid to the evaluation of all factors related to uncertainty and validation. It is the view of the PPR Panel that on this problem no clear answers and guidance are given.

The PPR Panel has concluded that the *Report* is a very promising vision for higher tier approaches to risk assessment but that it needs to be revised before it can be accepted as guidance to be used in an appropriate and consistent way by risk assessors.

DOCUMENTATION PROVIDED TO EFSA

1. FOCUS (2005). "Landscape and Mitigation Factors in Aquatic Ecological Risk Assessment (Vol. 1 and Vol. 2)". The Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. SANCO/10422/2005, version 1.0, May 2005.

REFERENCES

Brown, CD, Dubus IG, Fogg P, Spirlet M & Gustin C (2004). Exposure to sulfosulfuron in agricultural ditches: field monitoring and scenario-based monitoring. Pest Manag. Sci. 60: 765-776.

EFSA (2004). Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA on the appropriateness of using the current FOCUS surface water scenarios for estimating exposure for risk assessment in aquatic ecotoxicology in the context of Council Directive 91/414/EEC. 14 December 2004.

EFSA (2005a). Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from Commission related to the evaluation of dimoxystrobin in the context of Council Directive 91/414/EEC. 16 February 2005.

EFSA (2005b). Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the assessment of the acute and chronic risk to aquatic organisms with regard to the possibility of lowering the uncertainty factor if additional species were tested. 14 December 2005.

EFSA (2006a). Opinion of the Scientific Panel on Plant Protection products and their Residues on a request from the Commission on the safety of aldicarb MRLs. 19 October 2006.

EFSA (2006b). Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from the EFSA related to the aquatic risk assessment for cyprodinil and the use of a mesocosm study in particular. 01 March 2006.

EU (2006). “Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy” (EU Water Framework Directive - WFD). Official Journal (OJ L 327), 22 December 2000.

FOCUS (2001). “FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC”. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2 final (May 2003). 245 pp.

FOCUS (2006). “Pesticides in Air: Considerations for Exposure Assessment”. Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 draft 1 (13 July 2006), 200 pp.

Jarvis NJ, Hollis JM, Nicholls PH, Mayr T & Evans SP (1997). MACRO-DB: a decision-support tool for assessing pesticide fate and mobility in soils. Environmental Modelling & Software 12: 251-265.

Kop, J. (2001) MSc thesis IMAG Wageningen 77pp.

Leistra M (2005). Estimating input data for computations on the volatilisation of pesticides from plant canopies and competing processes. Alterra Report 1256, Alterra, WUR, Wageningen, The Netherlands, 80 pp.

Liess M (2002). Population response to toxicants is altered by intraspecific interaction. Environmental Toxicology and Chemistry: 21 (1), 138-142.

Liess M & Von der Ohe P (2005). Analyzing effects of pesticides on invertebrate communities in streams. Environmental Toxicology and Chemistry; 24 (4): 954-965.

SETAC (2005). EU & SETAC Europe Workshop (2003), Le Croisic, France. Effects of Pesticides in the Field. Editors: Liess M, Brown C, Dohmen P, Duquesne S, Hart A, Heimbach F, Kreuger J, Lagadic L, Maund S, ReinertW, Streloke M, Tarazona JV. ISBN 1-880611-81-3 (alk. paper). 1. Pesticides – Environmental aspects – Congresses. I. © 2005 Society of Environmental Toxicology and Chemistry (SETAC).

US EPA (1997). Guiding principles for Monte Carlo analysis. US Environmental Protection Agency, Risk Assessment Forum, Washington DC.[4]

Van de Zande, J.C., Holterman, H.J. Michielsen, J.M. G.P. and Stallinga, H. (2006) Temporal and spatial variability of spray drift around a sprayed field. Aspects of Applied Biology 77 295 - 302.

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[4] Available at: www.epa.gov

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APPENDIX I: GLOSSARY

ASCALE	Aggregate half-width. MACRO parameters for pesticide leaching in structured soils. Controls the movement of water and solute between the micropore and macropore domains.
CMA	Chemical Monitoring Activity
D2, D4, D6, R4	FOCUS Step 3 scenarios
EC	European Commission
EU	European Union
FOCUS	Forum for the Co-ordination of pesticide fate models and their Use
$FOCUS_{SW}$	FOCUS Surface Water
GAP	Good Agricultural Practice
GIS	Geographical information system
K_{OC}	Organic carbon adsorption coefficient
l/kg	Liter/kilogramme
LRA	Landscape-level risk assessment
MAC	Maximum acceptable concentration
MACRO	a physically-based one-dimensional numerical model of water flow and reactive solute transport in field soils
mesocosm, microcosm	Specifically designed model ecosystems used to investigate pesticide effects on communities of organisms, and/or the environmental fate of pesticides. The Guidance Document on Aquatic Ecotoxicology (EC, 2002) defines microcosms as indoor multi-species tests and mesocosms as outdoor multispecies tests. This definition is in line with other relevant publications (e.g., Campbell *et al.*, 1999). The PPR Panel follows that definition. Mesocosm are also larger than microcosms.
MS	Member State
PEARL	Pesticide Emission Assessment at Regional and Local scales
PEC	Predicted Environmental Concentration
PPR Panel	Scientific Panel on Plant Health, Plant Protection Products and their Residues
PRAPeR	EFSA's Pesticide Risk Assessment Peer Review Unit
PRZM	Pesticide Root Zone Model
RA	Risk Assessment
DG-SANCO	European Commission Health and Consumer Protection Directorate General
SETAC	Society of Environmental Toxicology and Chemistry
SW	Surface water
TER	Toxicity-Exposure-Ratio
TOXSWA	Toxic substances in surface waters; describes the exchange flux between water and atmosphere by the film model of two laminar layers at an interface.
Uncertainty	Uncertainty results from limitations in knowledge, for example if the measurements are subject to experimental error or if the extrapolation is approximate.
Uniform Principles	Annex VI of Directive 91/414/EEC: establishing common criteria for evaluating products at a national level were published on 27 September 1997 (OJ L265, p.87).
US EPA	United States Environmental Protection Agency
WFD	Water Framework Directive

APPENDIX II: LIST OF FOCUS RECOMMENDATIONS AND REFINEMENTS

No.	FOCUS Recommendations
1	Ecological risk assessment for the aquatic compartment to support Annex I listing should remain at the field scale. The influence of landscape on the risk assessment should be evaluated by dividing the landscape into parcels in order to investigate how parameters influencing risk at the field scale are distributed within the wider environment.
2	There is already sufficient evidence to implement certain measures into ecological risk assessment and it is recommended that this is done immediately. Authorisations of products that present unacceptable ecological risk under standard use conditions can be made subject to the application of suitable restrictions ensuring mitigation of the risk. These mitigation measures should be grouped by the extent to which they reduce exposure in the following categories: 50, 75, 90, 95 and 99%. The Work Group has adopted a reasonable worst-case approach in assigning measures to different categories (e.g. exposure reductions based on larger datasets are assigned as a nominal 10^{th} percentile of the actual range of efficacy).
3	For these reasons, it is recommended that a sequential procedure is adopted for incorporating mitigation measures into ecological risk assessment (Figure 1).
4	Whereas mitigation of spray drift is generally well-developed, further work is recommended as a priority to develop mitigation measures for exposure via surface runoff and drainflow.
5	It was agreed that the impact of such influences may be significant and that further work is required to develop and evaluate such approaches. However, as the scale of the risk assessment currently remains at field level, it is not recommended that such landscape processes are implemented into the assessment at the present time.
6	It is recommended that the maximum values identified in Table 5 act as an absolute cap for the incorporation of mitigation into risk assessments for Annex 1 listing (more differentiated maxima can be derived on a case-by-case basis according to the use conditions and options for mitigation).
7	Any change to the Step 3 scenarios is considered to be a Step 4 calculation and this should be clearly stated in the monograph.
8	To support any proposal for exposure mitigation, it is appropriate to demonstrate the potential effect of the mitigation through the use of refined Step 4 modelling.
9	It is strongly recommended that the location of additional scenarios should follow the procedures for overlaying data (i.e. soil, climate, slope, cropping) outlined by the FOCUS surface water scenarios group.
10	It is recommended that probabilistic methods can be applied as one of the approaches to refining assessments of exposure and/or effects at Step 4 and that this conclusion is equally applicable for the aquatic and terrestrial compartments.
11	The group does not recommend routine inclusion of catchment modelling into ecological risk assessment to support Annex I listing, but these models may be useful in linking the requirements under 91/414/EC with those of the Water Framework Directive.
12	Appropriate monitoring data for example compounds can provide support for refined or higher-tier risk assessments (e.g. landscape assessments, catchment modelling, probabilistic techniques).
13	When using landscape analysis to support higher-tier assessments, a full justification should be provided for the approach used to generate and analyse data and of subsequent use in modelling.
14	The rationale and justification for the site selection should be thoroughly documented.
15	For complete understanding and transparency, when GIS and landscape-level information are used at Step 4, a thorough description of the GIS data, processing and methodology should be presented in the report so that the reader can properly evaluate the process and the results.
16	If not well documented in the site selection process, an appropriate EU-wide examination should be conducted to set the results for the site/region that has been examined into a broader context.
17	It is therefore recommended that in the future, ecological scenarios are further developed to accompany the fate scenarios at Step 3. The work would need to be accompanied by a consideration of use within regulatory practice and clear demonstration of the area and/or environmental conditions for which a particular scenario is representative.
18	Further work is recommended to differentiate these more resilient water body types from permanent waters.
19	When establishing ecological scenarios, it is recommended that typical physical and chemical characteristics are included.
20	It is recommended that when establishing ecological scenarios, due attention is given to defining those ecological factors that may also influence fate processes.

21	Further development of the basic science, experimental options and modelling in this area is recommended.
22	It is recommended that research into these approaches (Calow, WEBFRAM,FreshwaterLife) is supported and continued in the future.
23	A new working group should be considered to further improve landscape analysis, modelling and mitigation approaches.
24	A new working group should be considered to develop the ecological characteristics of the FOCUS surface water scenarios for use in higher-tier exposure modelling and effects assessments.
25	Whilst the work presented here has focused on aquatic systems, many of the methods and approaches may be transferable to the terrestrial compartment. Nevertheless, complementary approaches should be developed for terrestrial systems in the future.

	Boxes in Volume 2 / Refinements
1	Sorption: Practical Step 4 refinements within the FOCUS modelling framework
2	Photolysis: Practical Step 4 refinements within the FOCUS modelling framework
3	Modelling of metabolites within the FOCUS modelling framework
4	Formulations: Practical Step 4 refinements within the FOCUS modelling framework
5	Drift: Practical Step 4 refinements within the FOCUS modelling framework
6	Dry deposition: Practical Step 4 refinements within the FOCUS modelling framework
7	Foliar dissipation and washoff: Practical Step 4 refinements within the FOCUS modelling framework
8	Runoff and erosion: Practical Step 4 refinements within the FOCUS modelling framework
9	Mitigation of runoff and erosion: Practical Step 4 refinements within the FOCUS modelling Framework
10	Drainage: Practical Step 4 refinements within the FOCUS modelling framework
11	Colloidal transport: Practical Step 4 refinements within the FOCUS modelling framework
12	Transport in water bodies: Practical Step 4 refinements within the FOCUS modelling framework